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Fred Eckel, MS
Executive Director

Executive Director's Perspective

Musing from the Hill

Change in Pharmacy

When I took over NCPhA, I thought we might make fast dramatic changes that soon would be obvious to everyone. That has not happened. As we take two steps forward, we seem to take one step back. This issue of the Journal will be the last one that Jennifer Stamer will produce as a full-time NCPhA Employee. We are indebted to Jennifer for staying the course during the transition. I could not have done it without her and she will be missed. As we find new help to keep the Journal production on schedule, I anticipate that you will find it a smooth transition although I might have a few more gray hairs.

NCPhA continues to work with the Health Care Oversight Committee to gain passage of the revised Pharmacy Practice Act. President Jackson and Mike James have been particularly active in this effort. Through working with the Division of Medical Assistance, the Legislature and the Governor's office, we believe we have been successful in preventing a reduction in the Medicaid Pharmacy Fee for 1998. However, NC Pharmacy will need to work cooperatively with the Medical Community to control drug costs or we may be faced with a fee reduction possibility again.

In this issue we feature three articles which contain an important message. Our first article is on Quality. As we change our practice focus to pharmaceutical care, we must be able to demonstrate the outcomes achieved. We must be able to assure our constituencies (patients, payers and regulators) that we are doing the right thing in the right way. Measuring the quality of our work is one tool we will need to use.

Under the title, "Educational Session Teaches How to Ask for the Money," we review an educational session conducted at the recent APhA meeting. I am convinced that we need to explore new sources of revenue for pharmacy to remain viable. It will be nearly impossible to increase dispensing fees unless pharmacists start saying no to the humiliating fees being offered today. Even if we do get an increase, it will probably not be enough to meet our financial needs. Therefore, we have to start asking people to pay for those services that today we give away. We also need to identify new patient care services, which will translate into new revenue sources. This article suggests how to communicate appropriately to get patients to buy into these new services.

The NC Center for Pharmaceutical Care (NCCPC) continues to promote training programs that represent new patient care services. NCPhA's Socioecomonic Seminar on March 18, 1998 in Greensboro, NC will have workshops lead by NC pharmacists which will focus on new patient care services they are offering and getting paid for. NCPhA is committed to helping you succeed as a pharmacist and have committed our resources to this goal.

The last article in this series is an editorial piece by Smith and Berger that reminds us that during this transition to pharmaceutical care, we need each other. I believe that unless all facets of pharmacy are successful it will be hard for any one facet to do well. That is why we need to support each other today more than any other time in my professional life. A new Organizational Structure is one way to help accomplish this. Another way is to share our successes. This Journal looks forward to publishing the successes of North Carolina Pharmacists.

The Asheville Project has been continuing under NCCPC's direction. Data from the first six months of pharmacists' interventions in the management of patients with diabetes has been collected and analyzed. The data collection will continue for at least six more months. These results will be widely shared.

Finally, NCCPC is sponsoring a program at the Institute of Pharmacy in Chapel Hill, NC to bring together pharmacists from the Southeast who are involved with Certificate Training Programs in diabetes management for pharmacists. By working together, we hope to find ways to assure that pharmacists are included in the Federal Regulations to be eligible for reimbursement for diabetes education from the Medicare Program. NCPhA is committed to working collaboratively with the rest of NC Pharmacy to advance our professional opportunities. We need your continued membership and support.

Measuring and Improving Quality: Looking Ahead

Editor's Note: The perspective below is a summary of a longer article written by Kathleen Lohr, Ph.D., Director of Health Services and Policy Research at the Research Triangle Institute in RTP, NC. The original article was featured in Health Affairs, May/June 1997. This summary piece appeared in the December 15, 1997 issue of Quality Partners, Vol. 2, No. 6.

Operationalizing a Definition of Quality of Care

Quality of care can be defined in straightforward, operational terms - a prerequisite for mounting effective quality measurement and improvement programs. As the Institute of Medicine asserted in its landmark 1990 report on a strategy for quality assurance in Medicare [1,p.21] quality of care is "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." Four elements of this definition deserve emphasis.

First, health services should be understood to encompass a broad range of services that affect both physical health and mental health.

Second, a focus on both individuals and populations is now understood to be imperative. The quality-of-care community has historically targeted services that "users" receive; now it must also direct attention to the entire community, including "non-users" of care.

Third, the outcomes of health care measured in quality assurance/improvement programs must encompass a wide range of clinical and biological endpoints and, especially, health status and functional outcomes.

Fourth, health professionals must strive to stay up to speed with the dynamic knowledge base within their own disciplines and specialties.

What we now face are new challenges posed by demography; preventive, diagnostic, therapeutic and rehabilitative technologies' multiple approaches to managed care; evolving strategies for guidelines and evidence-based practice; and widening avenues for research.

Kathleen Lohr, Ph.D.
Director, Health Services and Policy Research
Research Triangle Park

Addressing Continuing and New Quality Concerns

Technical and interpersonal competence, overuse of unnecessary and inappropriate services and underuse of (or lack of access to) needed and appropriate services are the typical targets of quality measurement and improvement efforts. Mastery of clinical areas, effective communications skills and compassion are issues regardless of the health care system in question. In past years, when fee-for-service was the main approach to financing and organizing health care in this country, overuse of health care came to be seen as a significant quality problem; thus, our toolbox for evaluating quality of care has contained measures aimed chiefly at reducing the utilization of unnecessary or inappropriate services (and their attendant costs). With managed care (of many variants) rapidly emerging as the dominant form of the American health care system, the incentives to put serious ceilings on use of services prompt concern that underuse (or significant lack of access to care) will become the major problem.

Obviously, people do not get proper preventive, diagnostic or therapeutic services if they lack health insurance and delay seeking care or receive no care at all. Even those with insurance often face geographic, cultural, attitudinal, organizational or financial barriers that limit their ability to seek or receive care. Among the more worrisome areas are mental health and substance abuse care, services for persons with rare or complex diseases and long-term or rehabilitative care for the disabled and elderly. How quality is to be maintained in such circumstances and for such populations remains a significant unanswered question today.

Prevention and screening pose yet other challenges. Many managed care organizations (MCOs) are commit-

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ted to screening and to primary or secondary prevention, but providing these services is a cost in the short term. If MCOs come to believe that members using these services will not remain in the plans over the long run, then they may doubt that they can or will recoup those outlays by virtue of having, on average, a healthier membership. In fact, to the extent that people do not stay with plans over extended periods, it may be a competitor who gains from prevention-related expenditures of the original plan, making it even less attractive for a given plan to make such services easily accessible. Moreover, some plans may reason that it would be better to engage in various types of risk selection, such as recruiting healthier members or selecting against less healthy individuals, than to pursue aggressive preventive programs.

Attention to the outcomes of care, or calls for "outcomes management," should not trump evaluation of the processes of care. For methodological and cost reasons, assessing the processes of care may be the only practical approach to quality measurement in many situations. What is needed is more information on linkages between processes and outcomes, and between those and structural elements of health organizations and clinicians, as emphasized more than 30 years ago by Avedis Donabedian. McGlynn recently stressed the need for explicit, clinical criteria by which to judge any of these aspects of health care quality, a well-justified position, in my judgment.

Comparisons of practitioners, providers or plans on any measures of quality, whether process-oriented or outcomes-related, risk being wrong if they are not done with proper adjustments for case-mix, severity of illness, and the presence of other, or comorbid conditions. Uncritical reliance on technical adjustments and arbitrary cutoffs said to be statistically significant can yield "information" that is fundamentally misleading with respect to the patient's decision-making about health care plans, facilities or physicians. *Comparative* quality measurement thus poses many conceptual and technical problems for those in the quality-of-care field.

Combining External and Internal Quality Programs

Traditional quality assurance programs were oriented more toward individual practitioners and facilities, had a more regulatory cast and tended to be imposed from the outside. Newer quality improvement strategies [such as those employed by Medical Review of North Carolina, Inc., and Carolina Medical ReviewSM] tend to focus on systems of care, encourage providers to work at continually improving their performance, and be considered more of an internal, data-driven approach. Whether such "CQI" approaches ought to supplant the older types of quality assurance efforts, especially those of the public sector, is a matter of ongoing debate.

In my view, the country cannot rely solely on internal quality improvement programs. It does not do so in many other sectors, such as transportation or defense procurement, and there is obvious reason for it to do so in health care. Rather, we should acknowledge the need for certain external quality assurance efforts, including those of regulatory and public sector agencies as well as those of rigorous accreditation and certification programs in the private sector. Indeed, much as law and regulation are needed to ensure the proper functioning of competitive markets, law and regulation are fundamental to adequate performance of our health care system and the continuous quality programs and performance measurement within it.

Looking to the Future

This nation has always faced dilemmas in balancing access to care, costs of care and quality of care. We are in a fortunate position as we are able to build on an existing toolbox of measures and of understanding that both internal and external programs of quality assurance and improvement are needed. What we now face are new challenges posed by demography; preventive, diagnostic, therapeutic and rehabilitative technologies; multiple approaches to managed care; evolving strategies for guidelines and evidence-based practice; and widening avenues for research. The quality-of-care community will, without doubt, be up to these challenges in the years ahead.

References:
[1] Institute of Medicine. Medicare: A strategy for Quality Assurance K. N. Lohr, editor. Washington, DC: National Academy Press, 1990.

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Educational Session Teaches How to "Ask for the Money"

Offering patient-centered services that promote wellness, proper medication use and successful management of health problems is an essential component of pharmaceutical care, but pharmacists can't do it for free. Many find it tough, however, to ask patients to pay them for efforts outside the realm of traditional dispensing.

At a recent APhA Annual Meeting, consultant and speaker Vivian Quiring taught pharmacists better ways to describe the value of their services, so that charging fees is easier. As Quiring - a pharmacist herself- put it, she helped them learn "how to ask for the money."

"We're not used to peddling our services," noted one pharmacist when Quiring asked what fears get in the way of asking for payment. Fear of being rejected, fear of conflict, fear of under- or overcharging and fear of being asked to justify fees - not being able to explain properly- are among other barriers pharmacists cited.

Fear of being rejected, fear of conflict, fear of under- or overcharging and fear of being asked to justify fees...are among the other barriers cited.

Tips Quiring offered were geared toward helping pharmacists use the right vocabulary and present themselves in such a way that "asking for the money" comes naturally. Among them:

•Think not of "justifying" your charges. Instead, explain them. To justify puts you in the defensive mode.

•Talk to patients in simple, everyday language. For example, don't talk about "cognitive services," because they may have no idea what the term means. High cholesterol has several names - dyslipidemia, hyperlipidemia, hypercholesterolemia - and all of them are intimidating to the patients. If you must use a technical medical term, ensure that the patient understands it.

•Project professionalism in how you look, behave and speak. The patient should see a neat, well-groomed professional with a welcoming, friendly, caring demeanor. The environment should support your professional image:

-Keep the surroundings clean and tidy.

-Arrange health education literature and resources in a well-organized,pleasing way.

-Display your degrees, licenses and certificates of specialized learning.

-Be sure that other staff come across professionally, as well as, including technicians and clerks.

•Employ good listening and questioning skills. Rather than listening to respond, which may keep you from picking up the patient's entire message, listen to understand.

•Acknowledge patients' concerns and let them know you're concerned too. Examples of phrases that work:

-"I can see why you might feel that way..."

-"It certainly must be frustrating to need to take a medicine every day."

-"I agree that it may seem like an extra service."

•In describing your service, respond to the unasked question in the mind of every patient or customer: "What's in it for me?" Potential benefits might be feeling better, getting the most out of their medicine, understanding more about their disease, preventing health crises that have happened in the past, saving money or time or reducing physician visits.

• Practice ways of informing patients about fees so it becomes comfortable to you. Notice that in Quiring's examples, she avoids the word "but":

-"[describe service]... and there is a fee for this service."

-"These are additional services we provide, for a fee, to help people with ..."

-"Our pharmacy offers a special/new/expanded service that can help you, and there is a fee."

-"Would you be interested in knowing how this service can help you and what the fee provides?"

-"Would it be of value to you...?"

-"Are you aware that there is a fee for this service?"

-"Would you be interested in [describe service]? This program costs _____ and includes _____."

When talking with physicians about your services, emphasize benefits, such as better patient care, saving the physician time because they get fewer questions from the patient and an efficient way to stay informed about the patient's status.

Gain commitment from the patient to receive the service. Quiring acknowledges that how to "close" and ask for the client's business is one of the most difficult communication skills to perfect. Some helpful phrases:

-"Do you agree that this program/service would help you manage your disease/disorder better?"

-"Do you see how participating in this program will

Getting Patients to Buy In: Key Steps

•Identify appropriate candidates for your services.

•Initiate a discussion about your services through in-store conversations, phone calls, personal letters, flyers, posters, advertisements in your community newspaper, or announcements in your pharmacy newsletter.

•Acknowledge patients' concerns (about their health, about their treatment, about the cost of a pharmacy service) in an empathic way.

•Describe features of the service and benefit to the patient.

• Explain the fees, charges, and payment schedule.

•Gain commitment from the patient to participate in your program or service.

make it easier for you to...?"

Some of the words and sentences she suggests using may feel awkward. Quiring said, but with practice they will come more easily - and bring results. "They may sound corny to you at first," she said, "But the more you use them, the more comfortable you'll become."

For more information about Quiring's availability to do a workshop for your pharmacy organization, contact:

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Increase Persuasiveness with Specific Words or Phrases

Without realizing it, the things you say can undermine your good intentions and your efforts to come across professionally, according to communication expert Vivian Quiring. Words and phrases you use habitually may even antagonize the patient or create defensiveness. One rule of thumb is to focus on the positive: say what you can do rather than what you can't. Another is to avoid the word "but" because it tends to negate all the words that precede it. Better is to replace it with "and," which equalizes the two statements, or to use the word "however," which implies negotiation.

Examples of phrases that Quiring says promote good feelings and avoids defensiveness:

Instead of:	Better to say:
I'm really not sure...	Let me verify/confirm that...
I can't give you an appointment until tomorrow.	I can give you an appointment tomorrow.
I'll try to contact your doctor.	I'll contact your doctor [or if you really have to try]; I'll do my best to contact your doctor.
What's the problem?	What's your concern[or issue or question]? Is there something I can help you with?
Why... (e.g., Why didn't you ask me?)	Is there a reason?(e.g. Is there a reason you didn't call me?)
You should, must, have to, had better...	Have you considered...? Would you please...?
We provide that service, but there is a charge.	We provide that service and there is a charge.

It's Time to Share Our Successes

By: Robert E. Smith, Pharm.D., Professor of Clinical Pharmacy Practice and Bruce A. Berger, Ph.D., Professor of Pharmacy Care Systems, Auburn University

Recently, a community pharmacist in Nebraska discussed his pharmaceutical care practice. He described his innovative approaches for providing pharmaceutical care services to his patients, including, a hypertension program, a hyperlipidemia program, a lifestyle modification and weight control program, an asthma program and a diabetes program. He also mentioned his net profit for this past year had increased substantially since he had provided his patients with disease management care. This pharmacist commented that he approached one of the competing pharmacists in his community about providing some of these same services. The colleague told him that these services were not within the realm of pharmacy practice and he would not be providing them. Whether or not the second pharmacist accepted the invitation to expand his practice into disease state management is not important for this discussion. However, what is important and what was most impressive was this pharmacist's willingness to share his success with his colleague, and perhaps even more so, his offer to assist this pharmacist in developing these same services for his patients.

As a result of this example and through mutual discussion, we have given a great deal of thought to the need to develop a greater sense of interdependence among pharmacists and to change what may be the prevailing attitude that we are all competing for a scarce piece of a very small pie. Perhaps the pie seems small now, but to make it larger, an attitude of interdependence must prevail among pharmacists.

More recently, at a program on developing the pharmacist's role in a disease state management, an individual who was currently billing patients was asked if she might share her experienced with the other 150 pharmacists in the auditorium. She said no. Her attitude was the opposite of what we are advocating. However, we recognize that a competitive attitude does prevail among many pharmacists. Yet, we believe that our collective future existence depends upon all pharmacists having an interdependent attitude about sharing their professional practice experiences. We must discuss our professional and economic successes with each other if we ever hope to advance the practice of pharmacy beyond the simple acts of dispensing and counseling patients.

The basic premise for community pharmacy interdependence is that our collective success is dependent upon sharing our individual successes. If we desire health care payers to more fully compensate us for our services, then the standard of practice must progress to the point where most of us are submitting documentation for compensation for the patient care services we actually provide. The only way for this to happen is for us to share with each other what we are doing and help instill the courage within others to change their practices. The pharmacist pioneers of these innovative health care services must discuss with other pharmacists, even with the pharmacists in their own communities, what services they are providing, how they are documenting these services, how they are billing for these services, what percentage of their compensation claims are being paid, and how their patients are accepting these new services. If we keep our successes to ourselves, then the rest of the profession is unaware of possible innovative ways to advance and we collectively move at a slower pace; perhaps a pace so slow that, as a profession, we are unable to take advantage of the window of opportunity before us.

You say, why should we tell our competition what we are doing? Will they not emulate our success and decrease our chances of maintaining the net profit margin we have worked so hard to attain? The answer is simple. There are enough patients and dollars for all of us. For example, there are roughly 60,000,000 hypertensive patients in the United States. Sixty percent of these patients are overweight and over half of all hypertensive patients do not know they have the disease. Assuming approximately 40,000,000 patients would benefit from a pharmacist's lifestyle and weight reduction program as well as a hypertension program and that there are close to 50,000 community pharmacies in the United States, then the pharmacists in each pharmacy could provide disease management services for approximately 800 overweight hypertensive patients. If each of these patients provided for an additionally $500.00 annually in compensated services, each pharmacy would gross an additional $400,000 annually. This would be enough extra income for all of us. However, we may not get this additional income, if we do not share our successes and collectively raise the standard of pharmacy practice. Similar figures can be developed for diseases such as diabetes, asthma and hyperlipidemia.

Let's use the airline industry as an example of interdependence. The airline industry is very competitive, yet they share a common reservation system and for the most part they will honor each other's tickets in the event a

flight is canceled or overbooked as is often the case. All of the airlines benefit by agreeing collectively to provide these services for each others' passengers. Together they raise the standard of the airline industry so that more people will fly and every airline wins. In pharmacy, every pharmacist will win if we improve the profession collectively. If we hide our individual successes, then the collective forward progress of the pharmacy profession will be slower.

So, now that you are "convinced" that you should share your successes with your pharmacist colleagues, how should you do that? One way would be to write up your successes and send them for publication in your state pharmacy journal. and Health Affairs. Perhaps your state journal would even set aside a page or two of the journal for short innovative practice reports from pharmacists within your state. In addition, you could send a report to the Department of Pharmacy Care Systems at Auburn University and they could list your name, pharmacy, and innovative services on their innovative services Internet web site (www.auburn.edu/pcs.html) along with the names of over 300 other pharmacists. Finally, when you attend a state or national pharmacy meeting, speak out about your successes and failures. Other pharmacists can learn from both.

In addition, if you are not providing disease state management services, begin to do so now. Even if it is only one patient, that is a beginning. Think about this. There are 130,000 practicing pharmacists in the U.S. If only one-third of those pharmacists submitted documentation for compensation for services rendered to a patient with a chronic illness, the profession *collectively* would provide third parties with 60,000 pieces of evidence that this is not an isolated way of practicing. Our standard would be raised and the profession would be in a much better position to negotiate compensation for cognitive services. Initially, would every one get paid? Probably not. Would some? They already are. If you want to see who some of them are, go to the Pharmacy Care Systems web site listed earlier in this article. A collective, proactive submission of well-documented claim forms will have a tremendous impact on those providing the funding for health care in your state. And, it would only initially require focusing intensively on one patient per month.

Simply put, our collective future will be stronger if we share our successes. Those of you who are having success, please tell others how you are doing it. Your success will give another pharmacist the confidence and vision to move forward with their practice. Let's not hide our light under a basket. Let's share it and move the profession of pharmacy forward as rapidly as possible.

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HCFA Announces Delay in Surety Bond Requirement

The effective date for the surety bond requirement for home health agencies and durable medical equipment suppliers billing Medicare has been delayed. Although the Balanced Budged Act called for the implementation of this requirement by January 1, 1998, HCFA has announced a delay of this date. The surety bond for DME suppliers will not take effect until a final rule is published after a comment period. Publication of the proposed rule is not anticipated until January. The requirement for home health care providers to secure a surety bond will be issued "as soon as possible". The home health agency rule must be published before HCFA can lift its moratorium on identifying new Medicare home health agencies. With these delays, it looks like the earliest time for bond requirement will be March or April.

APhA, NCPA and some State Pharmacy Associations are working to modify or exempt the surety bond requirements for pharmacies that do a small amount of this business. We understand that NCPA is working with Senator Dorgan's staff to introduce corrective legislation at the start of the next session to exempt licensed pharmacies/pharmacists from the Medicare Surety Bond requirement. You can encourage and thank Senator Dorgan for his efforts by writing: Senator Byron Dorgan, 713 Hart Senate Office Bldg, Washington DC 20510-3405 or email: senator@dorgon.senate.gov.

For those interested in obtaining a Medicare Surety Bond the National Community Pharmacy Association has made arrangements with a carrier to make this service available. They can be contacted at 703-683-8200. Pharmacists Mutual Companies also offers this service. The can be contacted at 1-800-247-5930, ext 23 for the Surety Bonds Department and ask for Carol, Jill or Matt.

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A Comparison of the Efficacy and Tolerability of Warfarin and Coumadin

Despite the fact that Coumadin is a drug with a narrow therapeutic index and potentially serious adverse effects, physicians over the years have developed a level of comfort with its use. Although generic substitutes decrease the cost of medical therapy, they sometimes have not gained widespread use because of concerns of therapeutic inequivalence. This is particularly true with drugs that are associated with serious adverse effects. The approval of generic drugs as equivalent usually requires a single dose crossover study in which blood levels are compared over time. However, generic substitutes usually are not compared with their brand name products in crossover clinical trials where a clinical endpoint defines equivalence, which inadvertently furthers these bioequivalency concerns.

Warfarin Sodium Tablets from Barr Laboratories (WB) is a newly available formulation of Warfarin Sodium, cleared through the FDA's generic drug system, which has been shown to be bioequivalent with Coumadin (WD) manufactured by DuPont Merck Pharmaceutical Company based on the 4 bioequivalence studies in healthy males. In order to determine if these agents are safely interchangeable in terms of their safety and efficacy in a clinical setting, we conducted an observer blind, randomized, crossover study utilizing these two forms of Warfarin Sodium. The design was a two sequence three period study (that is either WB:WD:WD or WD:WB:WB). Patients were obtained from a Coumadin clinic at a VA Hospital. All had a trial fibrillation and had been on stable doses of Coumadin for at least six weeks prior to enrollment in the study. After confirming dose stability and control at baseline (a mean of three INR measurements, between 2-3, over a seven-day run-in period) patients were randomized to either WB or WD for 21 days (period A). Patients were then switched to the alternative drug for a further 21 days (period B). Following this, patients remained on the same period B agent for another 21 days (period C). The protocol specified conditions under which dose changes were required. Patients requiring dose changes were excluded from the primary analysis.

Fifty-five patients were enrolled into the study. Fifteen patients (10 on WD and 5 on WB) required dose changes and were thus not evaluable for the primary efficacy analysis. An additional patient (in the WB group) had an adverse event (chest pain) and was withdrawn from the study. Thus, 39 patients completed the study without dose change. Of the 39 patients included in the primary efficacy analysis, 20 were initially randomized to WB and 19 to WD. The mean baseline INR for the group initially randomized to WB from base line was 2.52 and for the WD group was 0.06 and in the WD group was 0.04. In period B, the change from the base line in the WB group was -0.09 and in the WD group was -0.22. In the final period, the INR from baseline in the WB group was 0.06 and in the WD group was 0.07. Estimates of the mean INR from the analysis were 2.43 for the patients taking WB and 2.38 for the patients taking WD (with intra-subject variances of 0.051 and 0.183, respectively). The interval hypothesis to test for equivalence of the two drugs (based on the 80-120% rule) showed that the treatment effect WB - WD = 0.046 met the criteria (90% CL: 95-109%) and thus demonstrated equivalence of the two drugs. There were no differences between the two drugs in side effect profiles.

Thus, in this randomized crossover trial, we have shown that WB and WD maintain stable anticoagulation, are equally effective and have a similar safety profile. This data would suggest that these Warfarin Sodium preparations can be safely interchanged with no additional monitoring requirements as a result of the switch.

Editor's Note: In NC, Warfarin is on the Narrow Therapeutic Drug Index List *(see page 15).*

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Narrow Therapeutic Index Drugs List

A revision in the Pharmacy Practice Act during the last session of the General Assembly provided for a list of narrow therapeutic index drugs. These are drugs that have less than a two fold difference in the minimum toxic concentration and minimum effective concentration in the blood or are those drug formulations that exhibit limited or erratic absorption, formulation dependent bioavailability and wide intrapatient pharmacokinetic variability that requires blood level monitoring. The North Carolina Secretary of Human Resources, after receiving advice from the State Health Director, the North Carolina Board of Pharmacy and the North Carolina Medical Board has identified the following drug products as being narrow therapeutic index drugs, in alphabetical order:

- carbamazepine (all dosage forms) [Tegretol, various others]
- digoxin (all dosage forms) [Lanoxin]
- lithium (all oral dosage forms, all salts) [Eskalith, Lithobid, Lithotabs, Cibalith, various others]
- levothyroxin sodium tablets [Synthroid, Levothroid, various others]
- phenytoin (all dosage forms, all salts) [Dilantin]
- theophyllin [Uniphyll, Theodur, Slo-Phyllin, Elixophyllin, Slo-bid Gyrocaps, Theo 24, Theocron]
- warfarin sodium tablets [BMS Warfarin, Coumadin, Warfarin]

A prescription for a narrow therapeutic index drug shall be refilled using only the same drug product by the same manufacturer that the pharmacist last dispensed under the prescription, unless the prescriber is notified by the pharmacist prior to the dispensing of another manufacturer's product and the prescriber and the patient give documented consent to the dispensing of the other manufacturer's product. The term "refilled" shall include a new prescription written at the expiration of a prescription which continues the patient's therapy on a narrow therapeutic index drug.

All other provisions of the State Product Selection Law, including the prescription format providing for "Dispense as Written" and "Product Selection Permitted" are still in effect.

News from the American Diabetes Association

Highlights from the Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus

New recommendations about the diagnosis and classification of diabetes mellitus have been published in the July 1997 issue of Diabetes Care, marking the first changes since 1979.

These recommendations were made by an expert committee and have been accepted and are supported by the American Diabetes Association, the National Institute of Diabetes and Digestive and Kidney Diseases and the Centers for Disease Control and Prevention.

A Summary of Major Recommendations

CLASSIFICATION

•Eliminate "insulin-dependent diabetes mellitus" (IDDM) and "non-insulin-dependent diabetes mellitus" (NIDDM).

•Keep the terms "type 1" and "type 2" but use Arabic rather than Roman numerals.

•Type 1 diabetes is characterized by beta cell destruction, usually leading to absolute insulin deficiency. It has two forms: Immune-Mediated Diabetes Mellitus and Idiopathic Diabetes Mellitus. Immune-Mediated Diabetes Mellitus results from a cellular mediated autoimmune destruction of the beta cells of the pancreas. Idiopathic type 1 refers to forms of the disease that have no known etiologies.

•Type 2 diabetes is defined as a term for individuals who have insulin resistance and usually have relative (rather than absolute) insulin deficiency. People with type 2 range from predominantly insulin resistant with relative insulin deficiency to predominantly deficient in insulin secretion with insulin resistance.

•A new stage of impaired glucose homeostasis called "impaired fasting glucose" (IFG) has been defined as a fasting plasma glucose of ≥ 110 mg/dl but <126 mg/dl. The stage called "impaired glucose tolerance" (IGT) is retained, defined as an oral glucose tolerance test value of ≥ 140 mg/dl but less than 200 mg/dl. Both IFG and IGT refer to metabolic stages of impaired glucose homeostasis that are intermediate between normal glucose homeostasis and diabetes. Although not clinical entities in their own right (in the absence of pregnancy), they are risk factors for future diabetes and cardiovascular disease.

•Gestational Diabetes Mellitus (GDM) is retained; however, selective screening, rather than universal screening, for glucose intolerance in pregnancy is now recommended. Low-risk women are: less than 25 years of age, normal body weight, have no family history of diabetes mellitus and are NOT a member of an ethnic/racial group with a high prevalence of diabetes (Hispanic, African American, Native American, Asian). No change is recommended to the current diagnostic criteria for GDM.

•A fasting plasma glucose of 110 mg/dl has been chosen as the upper limit of "normal."

DIAGNOSTIC CRITERIA

•Diagnostic criteria have been modified from those previously recommended (see chart on reverse side of this page). Three ways to diagnose diabetes are possible, but one—the fasting plasma glucose (FPG) test—is preferred. At this time, hemoglobin A1c (HbA1c) is not recommended for diagnosis.

•An FPG value ≥ 126 mg/dl (confirmed by repeat testing) is diagnostic for diabetes. This recommendation is based on new population-based data showing a sharp rise in adverse outcomes (i.e., microvascular complications) at or near this blood glucose level and an increased risk for macrovascular disease.

•The revised criteria are for *diagnosis* and are *not* treatment criteria or goals of therapy.

Diagnosing Diabetes

	TEST		
STAGE	Fasting Plasma Glucose (FPG)(Preferred)	Casual Plasma Glucose	Oral Glucose Tolerance Test (OGIT)
Diabetes	FPG ≥ 126 mg/dl (7.0 mmol/l)	Casual plasma glucose ≥ 200 mg/dl (11.1 mmol/l) plus symptoms***	Two-hour plasma glucose (2hPG)≥200 mg/dl****
Impaired Glucose Homeo-stasis	Impaired Fasting Glucose (IFG)=FPG>110 and <126 mg/dl		Impaired Glucose Tolerance (IGT) =2hPG≥140 and <200 mg/dl
Normal	FPG<110 mg/dl		2hPG<140 mg/dl

*The FPG is the preferred test for diagnosis, but any one of the three listed is acceptable. In the absence of unequivocal hyperglycemia with acute metabolic decompensation, one of these three tests should be used on a different day to confirm diagnosis.

**Fasting is defined as no caloric intake for at least 8 hours.

***Casual = any time of day without regard to time since last meal; symptoms are the classic ones of polyuria, polydipsia and unexplained weight loss.

****OGTT should be performed using a glucose load containing the equivalent of 75g anhydrous glucose dissolved in water. The OGTT is not recommended for routine clinical use.

Criteria for Testing in Asymptomatic, Undiagnosed Individuals

(adapted from Diabetes Care, Volume 20, Number 7, July 1997, p. 11)

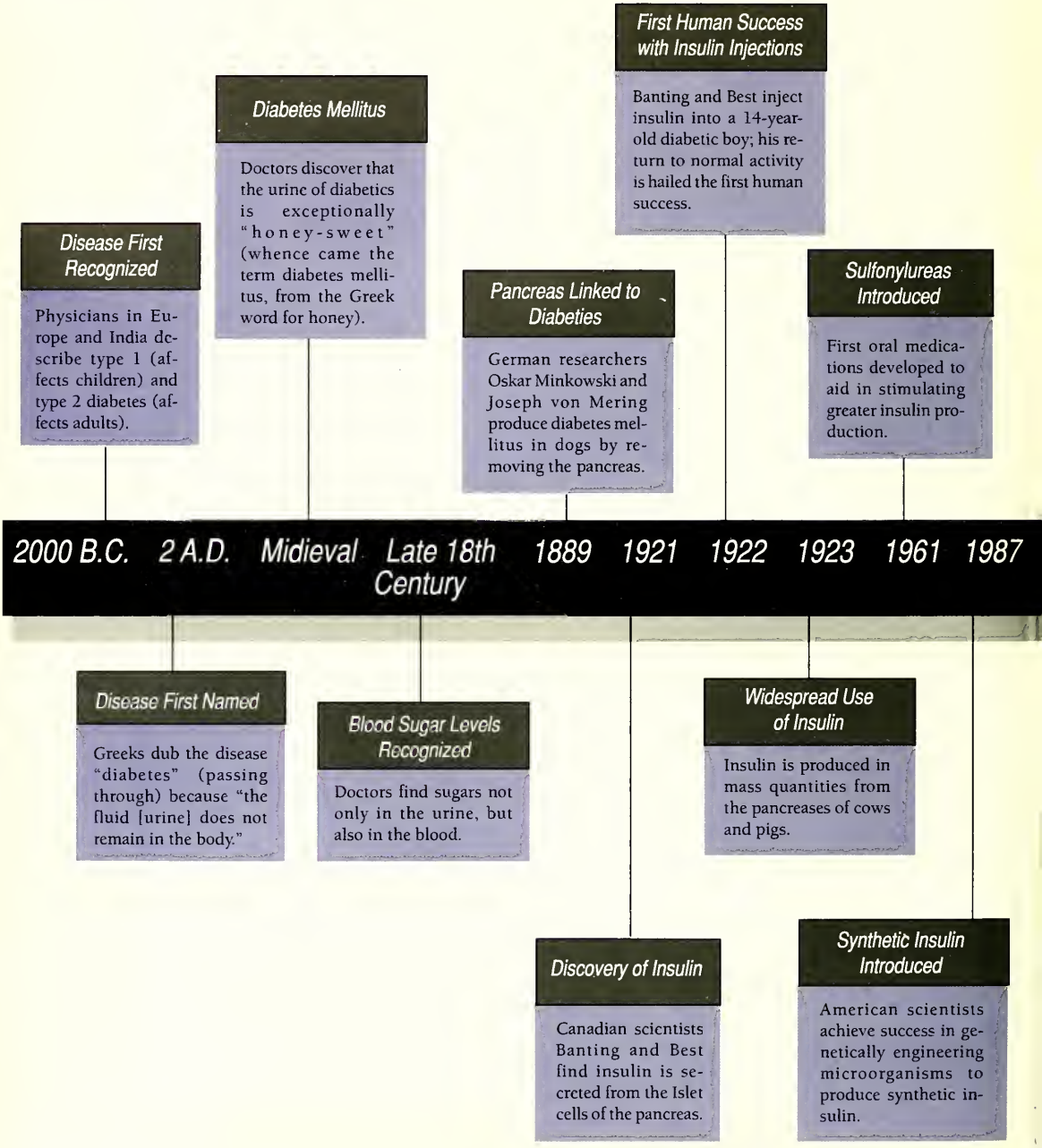
• Type 1 Diabetes: Testing presumably healthy individuals for the presence of any immune markers, outside of a clinical trials setting, is not recommended.

• Type 2 Diabetes: In asymptomatic, undiagnosed individuals, testing for diabetes should be considered in all individuals at age 45 years and above and, if normal, it should be repeated at three year intervals.

Testing should be considered at a younger age, or be carried out more frequently, in individuals who: are obese [≥ 120% desirable body weight or a body mass index (BMI) ≥ 27 kg/m^2], have a first-degree relative with diabetes, are members of a high-risk ethnic population (African American, Hispanic, Native American, Asian), delivered a baby weighing > 9 lb. or were diagnosed with GDM, are hypertensive (≥ 140/90), have an HDL cholesterol level < 35 mg/dl and/or a triglyceride level ≥ 250 mg/dl on previous testing, had IGT or IFG.

The FPG is the preferred diagnostic test because of its ease of administration, convenience, acceptability to patients and lower cost.

History of Diabetes


First Human Success with Insulin Injections
Banting and Best inject insulin into a 14-year-old diabetic boy; his return to normal activity is hailed the first human success.
Diabetes Mellitus
Doctors discover that the urine of diabetics is exceptionally "honey-sweet" (whence came the term diabetes mellitus, from the Greek word for honey).
Disease First Recognized
Physicians in Europe and India describe type 1 (affects children) and type 2 diabetes (affects adults).
Pancreas Linked to Diabetes
German researchers Oskar Minkowski and Joseph von Mering produce diabetes mellitus in dogs by removing the pancreas.
Sulfonylureas Introduced
First oral medications developed to aid in stimulating greater insulin production.
2000 B.C.
2 A.D.
Midieval
Late 18th Century
1889
1921
1922
1923
1961
1987
Disease First Named
Greeks dub the disease "diabetes" (passing through) because "the fluid [urine] does not remain in the body."
Blood Sugar Levels Recognized
Doctors find sugars not only in the urine, but also in the blood.
Widespread Use of Insulin
Insulin is produced in mass quantities from the pancreases of cows and pigs.
Discovery of Insulin
Canadian scientists Banting and Best find insulin is secreted from the Islet cells of the pancreas.
Synthetic Insulin Introduced
American scientists achieve success in genetically engineering microorganisms to produce synthetic insulin.

Alpha-Glucosidases Introduced

First medication introduced that decreases absorption of blood sugar during digestion, so blood sugar is eliminated rather than entering the blood.

1994 1995

Biguanides Introduced

First medication introduced in the US that reduces the amount of blood sugar produced by the liver, and reduces the amount of blood sugar the body absorbs when food is digested.

1997 A Landmark Year for Diabetes

FIRST THIAZOLIDINEDIONE INTRODUCED
JAN– Rezulin, (Troglitazone), first in its class, introduced. Targets insulin resistance directly through a unique nuclear mechanism of action. Helps the body make better use of its own insulin or that which is injected, enabling the blood sugar in the blood to enter cells.

FEDERAL GOVERNMENT INITIATIVE ANNOUNCED
JUNE– Federal Government announces the creation of the National Diabetes Education Program (NDEP), the government's largest diabetes effort to date to increase awareness of and improve the standard of diabetes care in the U.S.

REVISED NOMENCLATURE
JUNE– American Diabetes Association (ADA) announces new nomenclature for classifying diabetes. Type I diabetes (IDDM or juvenile) will now be referred to as "type 1" diabetes: Type II diabetes (NIDDM or adult-onset) will now be referred to as "type 2."

NEW DIAGNOSTIC GUIDELINES
JUNE– American Diabetes Association (ADA) announces new diagnostic guidelines on the diagnosis and classification of diabetes. The new guidelines recommend that testing for diabetes should be considered in all individuals at age 45 years and above.

NEW COMBINATIONS OF DRUGS APPROVED
AUG– The addition of Rezulin to a sulfonylurea has a synergistic effect, since both agents act to improve blood sugar tolerance by different, but complementary mechanisms.

2 BILLION DOLLARS FOR DIABETES
AUG– President Clinton announces the federal government will spend $2.1 billion over the next 5 years for diabetes treatment and research.

CDC ANNOUNCES RECORD LEVEL OF DIABETES
OCT– Centers for Disease Control and Prevention (CDC) announces that diabetes is at the highest level ever recorded in the US, with the number of new cases averaging 798,000 each year.

MEDICAL COMMUNITY PUSHES FOR USE OF NEW ORAL AGENTS
NOV– A study in the Journal of the American Medical Association (JAMA) shows that insulin is rarely effective in achieving optimal blood sugar control; medical community pushes towards use of new oral agents alone or in combination with insulin.

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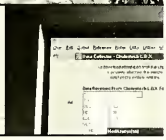

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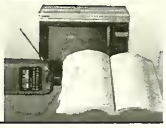

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NCPRN, Inc. Receives Funding, Goes Full-Time

After years of hard work and dedication by many, the North Carolina Pharmacist Recovery Network, Inc. now has a full-time office, and staff person. On December 1, 1997 an office was officially opened in Winston-Salem, and Executive Director, David Marley received their first phone call. Mr. Marley has over 8 years experience working with impaired professionals, and currently sits on the Advisory Council for the Pharmacists section of the University of Utah School on Alcoholism, and Other Drug Dependencies.

The history of the NCPRN goes back to the 1980's and the organization would not be where it is today had it not been for the pioneers of the early days, and supporters of today. Those people include; Dennis Moore who helped initiate the PRN concept in the 1980's; Al Mebane, Dan Teat, and Kathryn Kuhn who incorporated the NCPRN in 1991; Tim Ives and Alice Jordan who did a majority of the advocacy work until 1995, and the current Board of Directors who envisioned NCPRN getting where it is today.

Special thanks also goes out to NCPhA, NCSHP, UNC and Campbell Schools of Pharmacy, the Board of Pharmacy for their support, and to Jimmy Jackson and Mike James who helped get the necessary funding into the legislation.

Moving forward into the future, NCPRN has a number of activities planned. Most importantly, NCPRN is dedicated to spreading the message to impaired pharmacists and pharmacy students of NC that they are not alone, and that help available. It is important for these individuals, and is for the profession, to realize and understand, that chemical dependency in not a moral weakness. Rather, it is a disease recognized by the American Medical Association back in the 1950's, and has for a number of years been listen in DSM IV, as a psychiatric illness.

It is important to note that the recently proposed code of ethics addresses our issue as it states it is unethical *to practice while impaired*. It is not unethical *to be impaired*. Much like the diabetic who is not responsible for having diabetes, only for treating their diabetes. The addict is not responsible for having their disease, they are, however, responsible for treating it.

The code of ethics also addresses the responsibility of pharmacists to intervene accordingly on an impaired colleague. If you or someone you know is in need of assistance, you can reach the "PRN" by calling 336-774-9010, ***all calls are confidential***. If it is after hours, you can leave a message or page the Director at 336-208-6442.

Overcoming what has been for many, an emotional rather than intellectual response to this disease, will only be possible through education and information. NCPRN is committed to providing Continuing Education programs addressing chemical dependency in the individual, in the family and in the profession. In 1998, NCPRN has tentatively scheduled two, 5-6 hour CE programs to be held in Asheville in April, and Raleigh in November. Information regarding these programs will be mailed to all the pharmacists in the state as the dates become known.

If you are interested in learning more about NCPRN, or would like to become involved as a volunteer, they can be reached by any one of the following methods.

NCPRN, Inc.
3500 Vest Mill Rd
Suite #9
Winston-Salem, NC 27103

Phone: 336-774-6555
Fax: 336-774-9010
Email: NCPRN@msn.com

NCPRN HELPLINE
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WHEN

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April 17-19, 1998

AGENDA (abridged itinerary)

Friday, April 17 (7 p.m.-11 p.m.)
Registration
Opening Session
Coffee & Dessert

Saturday, April 18 (9 a.m.-11 p.m.)
Health Screenings
Continental Breakfast
Women's Health Issues
Dietary Management
Keynote Address
Lunch
Leadership Forum (APhA)
Time On Your Own
Dinner
Stress Management
Relaxation Workshop

Sunday, April 19 (8 a.m.-11:30 a.m.)
Prayer Breakfast
Women's Health Issues
Self-Defense

HOTEL INFORMATION

The Greenville Hyatt Regency has offered a special conference rate of only $82 per night (single or double occupancy) plus applicable taxes. Please contact the Hyatt's reservation department at (800) 233-1234 or (864) 235-1234 to make and guarantee your reservation with a credit card no later than 4/1/98.

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INSURANCE / FINANCIAL SERVICES

Patient Counseling: Prevention and Treatment of Skin Injuries; Part 2: Poison Ivy, Prickly Heat and Diaper Rash

Thomas A. Gossel, R.Ph., Ph.D.
Dean, and Professor of
Pharmacology and Toxicology
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph.,
Pharm.D.
Professor of Pharmacy Practice
University of Cincinnati
Cincinnati, Ohio

Goals. The goals of this lesson are to discuss common dermatologic conditions that are self-treatable with skin protectants, and to present information useful in counseling patients.

Objectives. At the conclusion of this lesson, successful participants should be able to:

A professional development program made possible by an educational grant from

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1. identify the causes and etiology of the conditions described;
2. exhibit knowledge of the treatment and means to prevent the conditions described;
3. show an understanding of the pharmacologic actions and adverse effects associated with the drugs used to treat the conditions; and,
4. demonstrate an ability to counsel patients on prevention and treatment of each of the conditions described.

Poison Ivy, Oak, and Sumac

Allergic dermatitis is reported to be an outcome of the contact with approximately 60 plants in the U.S. Poison ivy and oak are the leading causes of allergic dermatitis. The rash that results from contact with either plant is similar. Poison sumac causes comparable problems, but they are less common than those associated with poison ivy or oak. Most estimates state that at least 70 percent of Americans are allergic to these plants.

Poison ivy and oak reactions that follow contact with the oleoresin complex urushiol may be experienced throughout the year. They are much more common during the early spring and summer months, however, when plant growth is most active. Most questions about preventing and treating poison ivy and oak dermatitis reactions are asked during these seasons. The following information can be used in responding to these inquiries.

Treatment. Numerous home remedies have been formulated and proprietary products marketed over the years to help relieve symptoms of poison ivy and oak dermatitis. Many treatments that have not been proven safe and/or effective in modifying urushiol-induced skin reactions continue to be recommended and used widely. It should be noted that, at most, they may relieve itching and thus help protect underlying skin indirectly from damage from scratching.

Relief from itching is the primary goal of therapy. If itching is not checked, the sufferer may scratch the skin insatiably and damage it.

Rash and associated symptoms are usually self-limiting, normally clearing within one to three weeks with or without treatment. Unless secondary infection occurs, healing proceeds without serious complications.

Complications can occur including hematologic changes, kidney damage, dyshidrosis (lack of sweating), and pigment changes. Psychological reactions may be reported if the reaction is severe. For severe reactions, patients should be directed to a physician and advised not to self-treat their condition with OTC products. Usually a short-term course of corticosteroids is the best treatment.

Even though it is widely held belief, the exudate of poison ivy or oak dermatitis does not spread the condition. When blisters form, it may be beneficial to drain them carefully. Removing this fluid permits topically applied medications to penetrate more readily into the dermis where the stimulus for itching originates. It also eliminates some of the pressure from above the nerve endings to help relieve itching.

Draining is best achieved by inserting a needle at the blister margin on the skin's surface using aseptic technique, then applying slight pressure to the blister top to express the liquid. Extruded fluid can be absorbed onto

Table 1
Patient Information for OTC
Topical Hydrocortisone

Topical hydrocortisone is used for temporary relief of minor skin irritation, inflammation and rashes due to eczema, psoriasis, seborrheic dermatitis, poison ivy, oak, or sumac, insect bites, soaps, detergents, cosmetics or jewelry, and external genital and anal itching.

- To properly use this product:
  a. Wash your hands before and after use.
  b. Cleanse the skin area with soap and water and pat dry each time you are ready to apply this medicine, unless directed otherwise by your doctor.
  c. Only the medicine that is actually touching the skin will work. A thick layer is not more effective than a thin layer.
  d. Creams, ointments and lotions: Apply a small amount of the medicine to the affected area and spread lightly.
  e. Lotions: Shake the container well before applying the medicine.
- This product is for external use on skin only. Do not apply it into or near your eyes or mouth.
- Do not apply other creams, lotions or cosmetics on top of or underneath this medicine.
- Do not bandage the area unless directed by your doctor.
- If your condition persists or worsens, or if you have a constant irritation, such as burning or itching that was not present before you started this medicine, call your doctor.
- Do not use more often or longer than recommended on the label.
- Read all labels before using this product. If you have any questions, ask your doctor or pharmacist.
- Keep all medicines out of the reach of children and do not keep or use outdated medicines.

tissue or gauze or simply washed off. To help protect the tender underlying skin, the skin covering the blister should not be removed. Blisters on the face or genitals should be opened only by a physician.

Poison ivy and oak remedies may contain local anesthetics which interfere with generation and transmission of nerve impulses. Care should be observed when using any product containing benzocaine because it may incite sensitivity reactions in susceptible individuals. Most references which refer to the incidence of benzocaine-induced skin reactions are conflicting, and this incidence may be over-estimated. Nonetheless, patients sensitive to poison ivy and oak, who also respond to contact with other chemicals with allergic rash, should avoid benzocaine-containing products.

Antiseptics help prevent secondary infection. If itching is controlled so that tissue damage from prolonged scratching is minimized, infection is rarely a problem. Products with alcohol or phenol as the antiseptic are preferred, since these are also antipruritic. Benzalkonium chloride is inactivated by soap, so it is doubtful whether this antiseptic offers significant activity to warrant inclusion in OTC poison ivy and oak products.

Astringents include zinc and ferric oxides, potassium permanganate, tannic acid and aluminum acetate. These precipitate protein over the lesion, which causes the underlying area to contract and dry. Astringents also have mild antiseptic and tissue protecting actions. Except for aluminum acetate, the antipruritic action is not significant.

The switch of topical formulations of hydrocortisone from prescription-only to OTC status has increased self-treatment options for poison ivy/oak greatly. Patient information is listed in Table 1.

Benzoquatam is a newly-approved drug with a mechanism of action different from any other approved substance used to prevent poison ivy and oak allergic reactions. Also known as quaternium-18, benzoquatam is prepared by reacting a quaternary ammonium compound with bentonite (a clay). The resulting organoclay compound acts as a physical barrier to block contact of urushiol with the skin.

The OTC product (IvyBlock) is available as a 5 percent lotion. It is applied to the skin at least 15 minutes before possible exposure to poison ivy or oak. Patients should be advised to shake their container vigorously before applying. They should reapply the product every four hours for continued protection. Since it contains alcohol, the lotion should not be used around open flames.

Prickly Heat

Lesions of prickly heat (miliaria, heat rash) were described nearly 2000 years ago. Amelius Cornelius Celsus (25 B.C. to 50 A.D.) wrote about the pustules that appeared with sweating in his work entitled *DeMedicina*. Later, Pliny the Elder wrote of pimples caused by sweat in his treatise entitled *Natural History*.

Today we know that prickly heat is caused by obstruction of sweat gland openings. Sweat is trapped within the dermal layer causing localized irritation and inflammation, itching and generalized discomfort. The term *prickly* describes sensations variously referred to as *stinging or stabbing*. The disorder is visible as clusters of pinhead-size bumps.

Prickly heat is most prevalent during humid periods with temperatures above 90 degrees Farenheit and low wind velocity. It may appear during febrile illness when the skin is covered with heavy or obstructive clothing that causes intense sweating. Skin areas subjected to friction, such as belt line or skin underlying elastic edges of athletic work-out garments, are especially vulnerable. The condition also occurs when individuals sit or lie for extended periods of rubber or plastic sheets which retard sweating.

There are several types of prickly heat. *Miliaria crystallina* describes the condition caused by sweat duct ob-

struction within the stratum corneum, just beneath the surface of the skin. A large vesicle, one to two millimeters in diameter, forms over the skin surface. This condition occurs on the neck, underarms, and chest of infants, although it can appear on individuals of all ages. Lesions are usually asymptomatic until they are broken open by rubbing or scratching. Lesions filled with clear fluid, which can be broken easily with fingernails, are characteristic of *miliaria crystallina*.

Miliaria rubra describes the condition when obstruction occurs deeper within the epidermis. The name is appropriate because of its red coloration, *Miliaria rubra* may be confused with contact dermatitis or drug eruption. It is the only form of prickly heat characterized by inflammatory lesions. Sweating causes small red nodules (solid bumps) that overlay red vesicles. Itching and burning quickly follow any event which causes sweating.

Miliaria profunda describes obstruction of the sweat duct within the upper dermis. This condition occurs predominately on the trunk and upper legs. It results in flesh-colored or opaque papules. *Miliaria profunda* is often asymptomatic, and waxes and wanes with sweating episodes.

Although sometimes referred to as "gooseflesh," *miliaria profunda* should not be confused with *cutis anserina*. This is an evanescent (i.e., it disappears quickly) follicular disorder associated with cold and shock, rather than heat and sweating.

Any injury to the sweat duct can cause obstruction to sweat flow. Therefore, the patient may remain asymptomatic until sweating is stimulated and not necessarily relate the condition with the trauma that actually caused it.

Prickly heat occurs more frequently in infants, geriatrics, and other persons with atopic disease than in young and middle aged adults. *Miliaria crystallina* generally clears quickly without complication, with or without treatment.

Miliaria rubra may persist for two to three weeks while sweat ducts remain obstructed. With repeated skin damage, as that caused by persistent scratching, additional pathology appears, leading to *miliaria profunda*. Secondary infection may occur with *miliaria rubra*, including impetigo and folliculitis. It is, therefore, important to keep affected areas clean at all times.

When widespread obstruction to sweating occurs, as when 50 percent or more of the body surface is affected, anhidrosis (cessation of sweating) may result. In hot environments when body temperature regulation depends on properly functioning sweat glands, this may lead to serious complications.

Prevention and Treatment. Maliaria is best treated by preventing any stimulus that initiates sweating. This is accomplished by remaining in a cool environment and avoiding heavy work or exercise. Air conditioning may help individuals who are severely affected.

The patient's clothing should be loose fitting, light-weight, and absorbent. During periods when prickly heat is exacerbated, plastic diaper covers (rubber pants) should not be worn by infants.

Cool sponge baths with a colloidal oatmeal product followed by application of a cooling skin lotion are often helpful. Hydrocortisone lotion or cream may help reduce local inflammation causing obstruction, but hydrocortisone should be reserved for individuals two years of age and older, unless specifically requested by a physician.

Diaper Dermatitis

Diaper dermatitis (diaper rash, napkin rash, napkin dermatitis, nappy rash) is the most common skin eruption in the diaper area. An assessment of one-week-old infants showed that 35 percent had perianal dermatitis. Incontinent adults may experience similar irritant dermatitis.

Diaper rash is different from prickly heat, although they may appear the same physically. Diaper rash is also confused with other cutaneous disorders including candidiasis, dermatitis, psoriasis, scabies and herpes simplex. Specifically, diaper rash is a localized, red, inflammatory response that results from dermal contact irritation caused by urine, feces, or both.

Occasionally the rash may appear on areas other than those in contact with a diaper, such as the arm or face. When this occurs, it represents involvement of some factor other than the primary affliction causing the diaper rash. Infants with this condition should be examined by a physician before being treated with OTC remedies.

Diaper rash is categorized into four distinguishable forms. The most frequent is chafing dermatitis, noted by mild by mild redness and scaliness over the buttocks, waist and thigh-areas where the diaper touches the skin. A second type is sharply demarcated confluent redness confined to the skin folds. A whitish exudate is sometimes present.

In the third form, discrete, shallow ulcerations are noted over the entire diaper contact area. The fourth form is characterized by beefy-red confluent erythema over the diaper area with oval pustules around the outer edge of the

Table 2
Safe and Effective Skin Protectants

Ingredient	Concentration
Allantoin	0.5-2%
Alluminum hydroxide gel	0.15-5%
Calamine	1-25%
Cocoa butter	50-100%
Colloidal oatmeal Dimethicone	1-30%
Glycerin	20-45%
Kaolin	4-20%
Petrolatum	30-100%
Shark liver oil	3%
Sodium bicarbonate	1-100%
White pertolatum	30-100%
Zinc acetate	0.1-2%
Zinc carbonate	0.2-2%
Zinc oxide	1-25%

confluent area. This type of condition is compounded by fungal infection characteristic of *Canida albicans* (ulcerations with white exudate).

Diaper dermatitis is an irritant response that results when skin remains in continued contact with urine and/or feces. While variations occur, many experts attribute eruptions in the perianal area to feces, and rash on the waist, thighs and genitals to urine. Studies have investigated individual components of feces and urine to show which is responsible for the dermatitis. None of them has established an absolute cause-and-effect relationship.

Mechanical irritation also plays a role in development of dermatitis on the buttocks and other areas of pressure from the diaper. Irritation results when a diaper rubs against the skin constantly. It is increased when the diaper is fastened tightly, and characterized by a strong odor of ammonia.

Prevention and Treatment. Diaper dermatitis may be prevented and/or treated with the skin protectants listen in Table 2. Products containing zinc oxide and/or petrolatum are among the most effective and widely used remedies.

Products containing topical hydrocortisone (up to 1 percent, preferable 0.5 percent) are safe and effective for short-term application on children aged two years and above. Use should be restricted to less than one week to minimize risk of systemic toxicity from absorption. Absorption is enhanced by occlusion with rubber or plastic pants. Used correctly, steroid toxicity from hydrocortisone is rare. When toxicity is reported, it is usually in infants who are preterm, of low birth weight, or have severe inflammation or extensive denuded areas of skin in the diaper area.

Routine use should not be relied on since hydrocortisone treats symptoms without modifying their cause. Other OTC products containing a protectant such as zinc oxide should be tried first.

Boric acid has a long history of topical use on infants. It can be absorbed across irritated skin. Because of reported infant toxicity and fatalities, it should not be used to treat diaper dermatitis.

In some studies, quaternary ammonium compounds such as methylbenzethonium chloride have been shown to reduce occurrence of diaper dermatitis. But other studies have questioned their effectiveness, and some have actually shown them to cause irritation in the diaper area.

A candidal infection is suggested when there are isolated areas of dermatitis on the skin. These should be examined by a physician. Dermatitis that persists beyond 72 hours should also be evaluated professionally since there is increased association with *C. albicans* after this period.

The need for frequent diaper changes must be stressed to parents/caregivers. The diaper area should be changed as soon as possible after it becomes wet. The diaper area should be cleansed thoroughly with warm water and mild soap, and dried completely before a clean diaper is put on.

"Dry" diaper corners should not be used to wipe the baby's skin. Although they appear clean and dry, they may contain million of microorganisms. If these microorganisms are not removed by cleansing, the chance for infection is increased when the baby urinates the next time.

Infants who are highly susceptible to diaper rash may be placed in an open diaper during naps. Babies frequently urinate shortly after falling asleep. Therefore, they can be checked and the diaper replaced periodically if necessary.

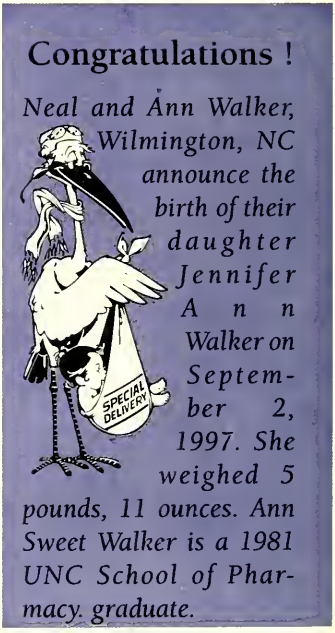
Counseling Patients

Consumer-directed advertising strongly suggests that certain types of diapers are better than others. The more fluid the diaper absorbs, the less contact it has with the skin. No study has demonstrated significant benefits of cloth over disposable diapers and vise versa.

Significant differences can be shown between commercially laundered and home laundered diapers. Commercial laundry services clean diapers at high temperatures which destroy all microorganisms very effectively. They also remove chemical irritants afterwards with thorough rinsing. These diapers are as clean and sterile as possible.

Individuals who wash diapers should use hot water, followed by thorough rinsing and drying in the hot cycle of the clothes dryer. Soaking diapers in a household bleach solution (diluted as directed on the label) or vinegar (one cup vinegar in a half-filled washing machine tub) prior to washing may help reduce the potential to irritate the skin.

Diaper dermatitis will not be experienced by all infants and incontinent individuals. OTC products intended for prevention and/or treatment of diaper dermatitis are not necessary for prophylactic use. These products ordinarily should not be used continuously.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Continuing Education Quiz

Patient Counseling: Prevention and Treatment of Skin Injuries; Part 2: Poison Ivy, Prickly Heat and Diaper Dermatitis

1. Diaper rash is caused by:
   a. a bacterial infection.
   b. a malfunction of the heat regulation mechanism in the hypothalamus.
   c. a contact irritation reaction.
   d. obstruction of sweat gland openings

2. Diaper rash is best prevented and/or treated by:
   a. using a skin protectant to prevent contact with the causative irritant.
   b. applying a first aid topical antibiotic ointment.
   c. preventing any stimulation that initiates sweating.
   d. taking aspirin as long as the child does not have a viral infection.

3. The oleoresin complex in poison ivy that causes allergic reaction is:
   a. plantago.
   b. cytosine.
   c. rhus toxica.
   d. urushiol.

4. All of the following are true about the blocking agent containing benzoquatam EXCEPT:
   a. it acts as a physical barrier.
   b. it is a clear solution.
   c. it should be applied prior to exposure to poison ivy.
   d. it should be reapplied every four hours for continued protection.

5. The primary goal of therapy with poison ivy is to:
   a. protect the blisters.
   b. prevent systemic toxicity.
   c. relieve itching.
   d. reduce fever.

6. Prickly heat is caused by:
   a. a bacterial infection.
   b. a malfunction of the heat regulation mechanism in the hypothalamus.
   c. contact irritation.
   d. obstruction of sweat gland openings.

7. Prickly heat is best prevented and/or treated by:
   a. using a skin protectant to prevent contact with the causative irritant.
   b. applying a first aid topical antibiotic ointment.
   c. preventing any stimulation that initiates sweating.
   d. taking aspirin as long as the child does not have a viral infection.

8. Which of the following is the preferred antiseptic to prevent secondary infections to poison ivy dermatitis?
   a. Alcohol
   b. Benzalkonium chloride
   c. Neomycin
   d. Polymyxin

9. Prickly heat lesions filled with clear fluid, which can easily be broken, are characteristic of:
   a. *miliaria crystallina.*
   b. *miliaria profunda.*
   c. *miliaria rubra.*

10. The exudate of poison ivy dermatitis:
    a. spreads the condition.
    b. does not spread the condition.

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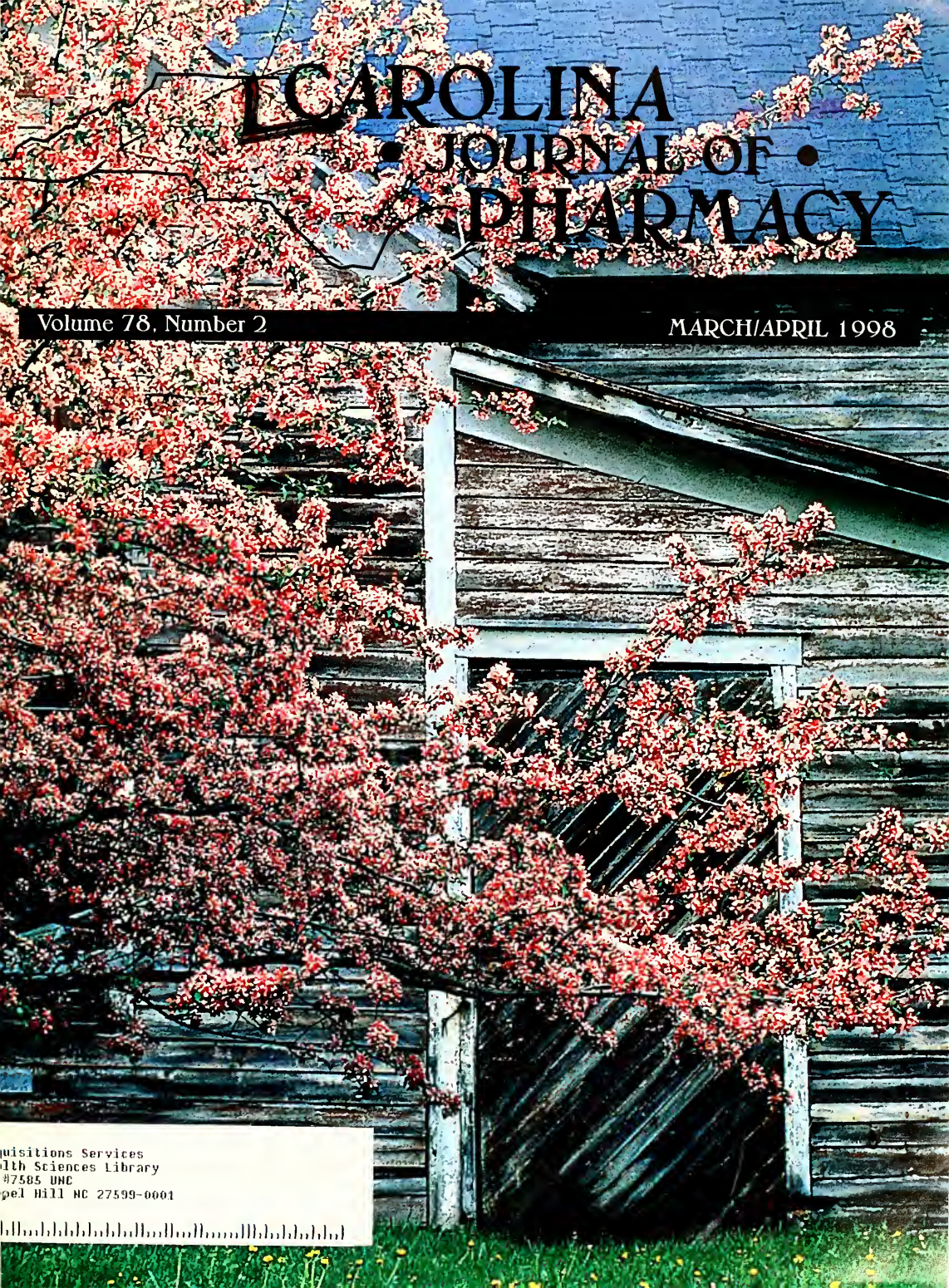

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Fred Eckel, MS
Executive Director

Executive Director's Perspective

Musings from the Hill

Laws, rules and regulations! Sometimes I feel that our profession is too regulated. Laws usually result from someone not doing something right. So to protect folks from the consequences of wrong actions, we pass laws. Sometimes these laws or regulations are more self-serving, though they are never promoted in this way. Although some would disagree with me, I think the recently passed Narrow Therapeutic Index Drugs List fits into this category. The argument is that because more and more pharmacists work for someone, usually a corporation, decisions about which drug product to use may be a corporate decision rather than the individual pharmacist's. Therefore, to protect the public, we have to pass legislation that takes away pharmacists' professional prerogative. Do I not remember a major effort from pharmacy 10 to 15 years ago to get antisubstitution laws repealed? And now we are starting the process of promulgating antisubstitution laws again. What drug class will be next now that we have this law in place? The published letter from the FDA in this issue of the Journal suggests that there are different opinions on the topic of Narrow Therapeutic Index Drugs.

Another concern today is how sensitive patient information could be used inappropriately. Health professionals need to gather and record information in order to care for patients. As different health professionals care for the same patient that information needs to be shared. Payors feel a need for information to be sure that payment claims are legitimate and appropriate. Such information getting into the wrong hands could be harmful, so it is understandable why there is a great interest in this area. Our feature article on patient confidentiality takes a look at this issue. The North Carolina Health Care Information and Communications Alliance (NCHICA) is an unique North Carolina non-governmental group committed to improving health care for our citizens and also maintaining a dynamic and innovative health industry through the application of the latest information and communications technology. NCHICA has developed a bill, the Health Care Information Privacy Act, which is being considered in the legislative short session. NCHICA is developing a proposal to have in place a paperless medical record system by 2008. Such a system could have a real impact on pharmacy practice, so pharmacists need to be actively engaged in this process. We haven't been so far, but we will be submitting a membership application jointly with NCSHP.

Also, we report on the Leaders Forum and the unanimously approved resolution to move forward with an "One Voice-One Vision" pharmacy organization in North Carolina. With the limited resources we have at our disposal in N.C. pharmacy such an approach just makes good sense. At our convention our members will be asked for their input into this process, which other states have suggested will take approximately two years. Make plans to join us in Chapel Hill on May 28-31 for this important meeting.

Finally, the process to find a permanent executive director marches on. We anticipate introducing this individual to the membership at the convention. By that time James Cooper Monroe Myatt's grandfather (that's me) will be ready to take some vacation time to visit him in Philadelphia. I am certainly enjoying my tenure at NCPhA. We have great potential, and I am committed to facilitating a smooth transition and continuing to work for pharmacy in North Carolina for many more years. By the way, have you encouraged anyone to join NCPhA recently? Our organization of 1836 members needs to grow if you expect NCPhA to do more to advance N.C. pharmacy.

Who needs to know?

Protecting your patients' privacy

by Jack Justice

Jack Justice, PharmD, MBA, FASCP and former director of Clinical Information Services for Revco, is the current president of Adherence Inc., a health care consulting firm. He is also an adjunct faculty member with the College of Pharmacy at the University of Cincinnati.

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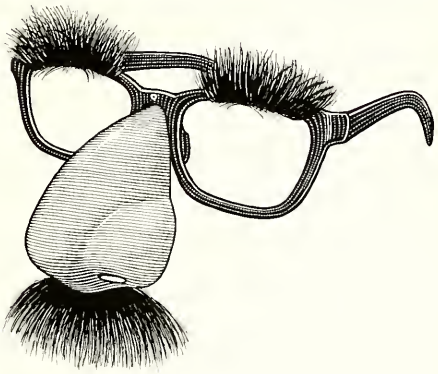

As the concept of pharmaceutical care gains ground, pharmacists are collecting far more sensitive information from patients than simply that related to the dispensing process. Dealing with this information is a serious concern for pharmacists, yet there are no clear laws or rules of law in pharmacy practice to guide the pharmacist, and very little informal training in just why it is important to prevent confidential information from being disseminated.

The necessity of clarifying this issue becomes apparent when one considers that even the well-known "doctor-patient privilege" (with respect to confidentiality) is actually a concession to common law. In other words, it is not mandated by legislation, but rather accepted as common and expected practice. This long privileged relationship is being tested in the current health care environment, especially with the advent of electronic transmission of patient data, to the extent that its status may in fact be codified in the near future. We should certainly expect that the evolving pharmacist-patient relationship will undergo similar scrutiny.

FIRST THINGS FIRST

There are certain concepts that appeal to us because they contribute to what we consider a greater or ultimate good. We describe "good" in this case as an affect that is desirable for us personally, for those around us or for society in general.

"Freedom," for instance, can be called a concept. The notion of freedom invites an assumption that there is some ideal state in which freedom would be complete or not require improvement, yet a description of the ideal would vary greatly among individuals. For instance, if 10 people are asked to describe "freedom," there will be 10 different descriptions, and virtually all would fall short of what would be ideal. The same is true for such concepts as autonomy, most people would indicate in some way that to be truly autonomous that one must be free to think or act without interference from others. How autonomy would be defined would be limited by the fact that we seem to know intuitively that absolute autonomy is abstract. We would concede, for instance, that we cannot freely act in ways harmful to others; no law should be necessary to tell us that we cannot simply set our apartment on fire because we are angry with the landlord.

With regard to privacy, most people understand that in order to be truly autonomous, we must be entitled to some degree of privacy. In the strongest possible terms we might describe our right to privacy as a sovereign right, irrevocably ours to enjoy and manage. For instance, it is hard to imagine anyone not condemning someone for reading another's diary without authorization. We should be able to keep private those things we wish to keep private. For instance, I can think of several reasons a person would not want people to know he or she was taking an anxiolytic. It would not be hard to imagine a situation in which this knowledge could be used to the detriment of the individual.

AND THEN TO CONFIDENTIALITY...

Confidentiality is rooted in the right to privacy as privacy is rooted in autonomy. On occasion, we will give private information to certain people with an understanding that the person will not, in turn, share the information with others.

The health information shared with the clinician in order to receive the anxiolytic is private, and it is reasonable

to expect that the clinician will hold it in confidence. This is true because it is commonly understood that private information provided to health professionals or gleaned by the professional during treatment of an individual should be considered confidential in nature.

Until now, there was no need to establish laws governing these assumptions, even though the information is of a nature that the patient would not want it to be known by everyone. Rather, it is information the patient has yielded sovereignty over, a decision that has become relatively easy based on the physician-patient relationship that has taken centuries to evolve. No professional should ever forget that such a yield in sovereignty by a patient is an expression of uncommon trust.

CONFIDENTIALITY

In the health care arena, individuals typically surrender some measure of privacy to professionals, yet feel that they ought to retain some control over information gathered by a health care professional during treatment.

In the past, when care was in some ways less complicated, a health care professional would not have thought of sharing information about a patient or her care, except perhaps with other professionals directly involved in the care of the patient, without first discussing it with the patient.

However, most patients would be astonished to learn how many people in a health care setting have legitimate access to what they would consider confidential information. One writer[1] presents a case of a patient who was concerned about the number of people who seemed to have access to his medical records while he was hospitalized. That patient was so concerned that he threatened to withdraw from treatment.

Upon inquiry, the writer found that many more people than even he would have thought indeed had legitimate needs and responsibilities that required them to examine the patient's chart. In fact, the hospital personnel with legitimate needs to view the patient's medical records numbered 75.

NORTH CAROLINA: Health Care Information Privacy Act

Bill Summary

- *Clarifies and "completes" N.C. law governing disclosures and uses of identifying health information, including patient's right to access and amend his/her medical records, for both paper and electronic records.*
- *Provides explicit protection for "identifying health information" and encourages the use of "non-identifying" information necessary for patient's care, unless patient objects.*
- *Requires "audit trails" for creation, use and disclosure of identifying health information*
- *Authorizes N.C. standards in accord with federal and industry standards, guidelines and requirements.*
- *Establishes civil liability, but provides "safe harbors"*
- *Does not supplant existing detailed regulation and protection for mental health, substance abuse, HIV and AIDS.*
- *Permits disclosure of "directory information" unless it reveals that the patient may be receiving treatment for sensitive conditions.*
- *Eliminates "quill pen" laws and recognizes "electronic signatures"*
- *Provides rules for subpoenas, court orders and other "compulsory" disclosures.*
- *Enables performances of audits (including peer review, QA, planning) by custodians, health oversight agencies and group policy holders.*

A copy of House Bill 925 may be found at ***http://www.ncga.state.nc.us/.html1997/bills/house/hbil0925.full.html.*** *This bill was developed by the Governor-appointed North Carolina Health Care Information and Communications Alliance (NCHICA).*

THREATS TO CONFIDENTIALITY

Threats to confidentiality exist throughout the health care industry, especially since it has come to depend on the ability to store and disseminate information electronically, and it has become extremely difficult to limit access on a need-to-know basis.

Beauchamp and Childress[2] provide a good example of this evolving problem: "If a company routinely offers medical examinations by a corporate physician, records are computerized and merged with all claims filed by an employee's private physician for reimbursement under corporate insurance policies. Many employees are concerned that this extensive two-track set of records presenting a medical history will be used against them."

This may be a legitimate concern for the following reasons: the private physician is chosen by the patient as an advocate, while the corporate physician is hired by and often serves as an advocate for the corporation. It can be argued, for instance, that the corporate physician has a more compelling interest to provide otherwise "confidential" information about a patient to the corporation than to protect the right of the patient to confidentiality.

Say for instance, the patient is an employee involved in critical work requiring unusual concentration and in which failure to perform well might lead to his harm or the harm of others, and the physician discovers that the patient is taking an antidepressant that routinely affects cognitive function. If there is a possibility that the antidepressant may impair cognitive function of the patient, what should be the physician's priority — the right of the patient to confidentiality, or the right of the corporation to protect its interests or those of its customers?

EXCEPTIONS TO CONFIDENTIALITY

It should be understood that the right to confidentiality cannot be absolute. A good example of this involved a court decision concerning information provided to a psychotherapist by his patient[3].

A mental patient told his psychotherapist that he intended to kill a former girlfriend. The psychotherapist had the name of the woman and would have been able to communicate the threat to her or the police, but he failed to do so. Tragically, the patient later carried out his threat and killed his former girlfriend.

The court held that the psychiatrist was liable for failing to initiate steps to warn the victim, reasoning that the public policy of favoring protection of patient-psychotherapist communication must yield to the extent to which disclosure is essential to avert danger to others. The privilege ends where public peril begins.

This is not all that unusual, and one could argue that the psychotherapist should have logically reasoned so. Many statutes reflect this thinking in requiring clinicians to report certain contagious diseases and suspected child abuse to authorities. These are long-standing laws that clearly focus on protection of others.

Likewise, it is a common practice that clinicians are required to report patients with gunshot and knife wounds. The argument here is different, but similar in that the requirement to report is based on the need to apprehend wrongdoers so that others may be protected from harm.

BREACH OF CONFIDENTIALITY AND/OR PRIVACY

Practitioners should understand that there is a difference between breach of confidentiality and breach of privacy, at least in the sense in which we are discussing these issues. As stated earlier, confidential information is provided voluntarily or gleaned by the professional during treatment. If the patient agrees beforehand that such information may be shared with others (spouse, employer, insurer, etc.), no breach of confidentiality occurs if the information is shared.

A breach of confidentiality, in other words, occurs when information about the patient or his care is shared with those who do not have authorization to receive the information. In assigning possible blame if a breach of confidentiality is claimed, one must look at whether the person to whom the information was provided had authorization to receive it, and if not, whether there was a compelling reason that justified the breach.

Authorization, by the way, may be situationally necessary. A pharmacist must understand this in discussing patient information with others. Many of the 75 people who had authorization to view confidential patient information in the earlier example had what might be considered situationally necessary authorization, though not expressed or acknowledged, which may not have been in line with the patient's understanding of common practice.

For example: The physician's duties are well-defined as a primary care role. In other words, authorization is expressed and acknowledged in common practice, and it would be very hard to argue that the physician needs less than complete access to all components of the patient history to fulfill the primary care role.

This is perhaps not the case for others on the health care team, such as physical therapists, respiratory therapists, dietitians and patient assistance personnel. One could argue that situational necessity provided for a physical therapist's need to see x-rays without formal authorization; it would be much more difficult, on the other hand to justify her having access to information concerning the drug or psychological profile of the patient. The prudent primary care practitioner, physician or pharmacist should take care that this is understood and not casually discuss confidential issues of patient care with those who do not have a justifiable need to know.

A very serious problem arises when there is a breach of privacy as discussed in this context. Remember that a breach of confidentiality involves information over which one has been granted authority. It is quite different if no such authority exists. To view information about a patient when you have no authority (situational or otherwise) to do so is a breach of privacy, and to disseminate that information is unforgivable. In the case of an employee at, for instance, a long-term care facility who breaches a patient's privacy, there is no need for discussion. The employee should be summarily discharged.

THE SERIOUSNESS OF BREACHES OF CONFIDENTIALITY

It is understood in all ethical discussions that confidentiality is important and that the right to confidentiality must be protected. Since trust is an important requirement of civilized behavior, if confidentiality were not so viewed it would be difficult for any society to function well.

When an ethical obligation, individual or collective, is truly important, its expression is often seen in laws. Though specific laws in respect to confidentiality in the physician-patient relationship are lacking, the inviolable nature of the trust finds legal expression in at least two forms: (1) State evidence codes contain a testimonial privilege for confidential patient communication, and (2) outside the courtroom, tort law protects patient confidentiality by allowing litigation for harm caused by the unauthorized release of patient communication[4].

Since tort law is apparently accepted as a means of clarifying contemporary problems involving confidentiality, and the issue of confidentiality is dynamic, professionals must routinely consider whether information they acquire can be freely disseminated or should reasonably be considered confidential and protected.

In pharmacy, for instance, there is a great deal of discussion on how and with whom patient information can be shared. If certain information is shared and this results in real or perceived harm to patients, it will be resolved in tort law. Say, for example, that a pharmacist provides information to a manufacturer concerning patients taking a particular drug. The manufacturer, in turn, provides educational information to the patient about the common usage of the drug. A patient, however, understands that he is taking the drug for reasons other than those stated in the educational material and subsequently refuses to continue the medication. If any harm comes to the patient, it is possible to claim the harm was initiated by a breach of confidentiality on the part of the pharmacist.

A common sense approach to avoiding this problem might have been, for instance, to mail a postcard to each patient telling them about the availability of the educational material and inviting them to request it if interested (by return mail or via a toll-free phone number). The desire for the information would, in this case, have been that of the patient. For pharmacists in all areas of practice, being informed of a patient's diagnosis allows them to provide only that information relevant to the patient's care. Tort law may also clarify the issue of how electronic transmission of medical information should best be handled in order to protect patient confidentiality. Privacy and security of this type of confidential information is even being discussed in respect to information collected through the public health system[5].

Many urge that patient-sensitive data must be shared among health agencies in order to provided continuity of care. Take, for instance, the potential treatment of patients with multiple drug resistant TB. The patient may initially be seen and identified in one of a number of different facilities, including jails, emergency departments, homeless shelters or clinics for treatment of HIV. Patients at greatest risk may be those who are least likely to return for assistance or seek out a more appropriate treatment facility. Continuity of care might be enhanced if these facilities could share patient-sensitive data.

Assuming that care would be enhanced with shared information, one proposal is that privacy and security assurances also have common standards. In other words, all users of the information (recipients) should be required to honor the same privacy and security assurances expected

NCHICA

North Carolina Health Care Information and Communications Alliance

Focus Areas

- *Common Message Delivery System*
- *Computer-based Patient Records*
- *Confidentiality, Privacy & Security of Health Information*
- *Electronic Data Interchange*
- *Knowledge Resources for Health Care*
- *Telehealth*
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of the initiator of the information.

A state agency, for instance, may have an elaborate electronic system to protect and store patient-sensitive information but willingly share this information with other agencies in order to provide better care for patients. An agency receiving the information from the initiator should then have a legal obligation to protect and store the data in a manner equal to or exceeding that of the sender.

This policy, if it becomes public policy, is important to pharmacy. In practical terms, it implies that the pharmacists should take care to ensure that entities with whom patient-sensitive information is shared provide the same level of protection the pharmacy provides. The whole issue of confidentiality in respect to medical records is being addressed in legislation. Congress has received a mandate to legislate comprehensive medical records privacy legislation by August 1999, and is currently considering six separate privacy bills[6].

However, most patients would be astonished to learn how many people in a health care setting have legitimate access to what they would consider confidential information.

THE TEAM APPROACH AND CONFIDENTIALITY

The team approach in health care, especially in long-term or institutional care, is a valid way to manage limited resources or better manage their allocation in order to reduce health expenditures. By necessity, the team approach allows access to medical information to a greater extent than will other forms of care. Unless explained, this may run counter to the expectations of patients, who may well assume that the more traditional and strict physician-patient relationship is in place[7].

There are several things that can be done to ensure that the patient does not feel threatened by the team approach. The first is patient education, which helps the patient understand and accept the value of the team approach. Acceptance will make it easier for the patient to allow broader access by team members to what the patient considers confidential information. Second, many team members will already have a professional obligation to confidentiality but others may not. A fundamental exercise is to ensure that all team members — in fact, all personnel in contact with the patient — understand the importance of patient confidentiality, what it entails, and their obligation to protect it in respect to individual patients.

CONFIDENTIALITY AND COMPETENCE

The principles or rules of liberty, privacy and confidentiality are derived from the principle of respect for autonomy[8]. Adherence to this principle by others allows individuals to act as free moral agents, and the question arises as to whether this is bound to a patient's mental competence — an especially important question in long-term care. The answer is no, but is does place a burden on health care professionals. Care must be taken to continue to respect the principle of the right to autonomy, for mental incompetence is one situation in which the rights of the individual must, in many cases, be overridden by those charged with the patient's care. On the other hand, mental incompetence does not imply that an individual has become an object, or that his or her rights are permanently suspended in some way. Professionals should try to consider situations as best they can so that decisions will be in line with the wishes of the individual if competent. For example, one would not discuss confidential health information with others unless they filled the advocate role of making subsequent health decisions on behalf of the patient. In some ways a breach of privacy or confidentiality in the case of incompetence would seem less defensible, at least morally.

The ideals presented so far are expressed in most professional codes of ethics. A good example is the Code of Ethics for Pharmacists adopted by ASCP (1992)[9]. In part, the pharmacist is asked to (1) respect the convenantal relationship between the patient and pharmacist, (2) promote the good of every patient in a caring, compassionate, confidential manner, and (3) respect the autonomy and dignity of each patient.

THE REAL WORLD

Understanding the importance of the rights of autonomy, privacy and confidentiality is one thing. Applying them in the work environment is quite another. Health care is dynamic. As such, the individual professional must view his or her own efforts to protect these rights of patients as dynamic.

For example, a pharmacist introduced to the care of patients with communicable diseases (e.g. HIV) faces situations in which these rights are treated differently than if one is caring for patients in other settings. For instance, there are legal requirements for disclosure of certain information

involving contagious diseases that one does not normally see. The pharmacist is in a position to influence the health care environment in which he or she practices. With a personal commitment to protect patients' rights to autonomy, privacy and confidentiality, the pharmacist can set an example for other professional associates responsible for the care of patients.

Even though the intent would rarely be to purposefully breach individual rights, they are breached nonetheless. It would, for instance, be unusual in today's practice environment to find a primary care professional hesitant to discuss a patient's care with family members (especially the spouse), even if he or she had not first informed the patient of the intent to do so.

This lack of hesitance would probably exist, too, in sharing health information with other health care team members, irrespective of their need to know. Pharmacists should use these questionable practices to form their own approach to their obligations to protect patient confidentiality.

For example, in many clinical settings it can be observed that patient records are not handled with the care they deserve if the rights of patients are to be protected. Most consultant pharmacists can attest to the fact that patient records in institutional and long-term care facilities are too often easily accessible, occasionally even to the public. Such practices are intolerable, and calling attention to these inadequacies is just one example of how an attentive pharmacist can influence the environment in which he or she works so that the environment operates efficiently while the fundamental rights of patients are both respected and protected.

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Making a case for pharmacists

by David Smithwick

As the millennium approaches, N.C. pharmacists have the opportunity to lead the rest of the profession into the future. But, before we talk to lawmakers or insurance companies about our value, we should make sure that our case is as strong as possible. Perhaps part of the solution may be our state Medicaid program which is an integrated program that was not created to make profits for shareholders. However, the real responsibility lies in the institutions that make up our profession and the people that practice pharmacy in North Carolina.

The North Carolina Medicaid program recently considered a proposal that would lower the reimbursement rate for pharmacists from the current standard to a new rate near AWP minus 18-20 percent plus a $4-5 fee. This was in response to Governor Jim Hunt's initiative to allow no more than an 8 percent per year increase in Medicaid expenditures by the year 2000. The average yearly increase in Medicaid expenditures for the past 10 years has been about 18.8 percent while the drug budget increases at an annual rate of 19.4 percent. Pharmacy expenditures account for roughly 8.4 percent of total Medicaid dollars.

The reason for not lowering the reimbursement rate may be because of program officials' awareness that slashing pharmacy costs will be offset by increased costs in other aspects of the Medicaid program. That is certainly an idea that pharmacists should subscribe to. One of the fundamental flaws in the current health care cost-management system is the lack of integration between major medical insurance providers and pharmacy benefit managers (PBM). Our value as cost containers and disease managers will never be realized unless there is incentive for PBMs to move beyond lowering only the cost associated with drug dispensing.

Many in the profession of pharmacy claim that we offer value in the form of cost containment, disease management and improved patient outcomes through the provision of pharmaceutical care. If we can establish these assertions as fact, then Medicaid will be an ideal source of strength for the future of our profession.

Some of the challenges of strengthening our future rests on the shoulders of leaders in the retail pharmacy industry and academic sector. We need a concentrated effort to gather data that shows statistically significant cost savings and improved patient outcomes as a result of the efforts of pharmacists. Retail drug stores and chain organizations must provide settings for studies, financial investment and pharmacists. Academic institutions must provide more research programs, grant money and qualified professionals. Data is the key to our future. Creating new ways to generate profits will ensure that the profession grows and will continue to offer pharmacy schools a reason to teach the number of students that they now teach.

The majority of the challenge rests in those of us who currently practice pharmacy. While we claim that we should be paid for cognitive services, how many of us are truly qualified to provide quality pharmaceutical care? I recently received a survey from a pharmacy student asking me about microalbuminuria. I was embarrassed by the fact that I had no clue about the subject. How am I going to provide diabetes disease management when I am not an expert on the subject? Many of us are effective drug-use counselors, but opening avenues for greater income will not be initiated by adhering to OBRA.

If you want to be a player in the future of our profession, get certification as a diabetes caregiver. Learn how to give immunization shots. Learn how to monitor cholesterol levels. If you feel that we are not being given our due, make sure that you have a strong case before you ask for it. If we are given opportunities, and we appear unable to respond, the damage will be irreparable.

David Smithwick is a pharmacist at The New Kerr Drug at University Mall in Chapel Hill. The 1991 UNC School of Pharmacy graduate has been accepted into MBA school and plans to begin study this fall. His goal is to develop his business skills so that he can apply that knowledge to the pharmacy industry. As Smithwick said, "If the opportunity arises, I'd like to help the profession of pharmacy adapt to the current state of the health care system and even flourish in it."

FDA on Narrow Therapeutic Index Drugs

Dear Colleague:

As you may be aware, certain individuals and groups have appeared recently before state legislatures, state boards of pharmacy and drug utilization review committees, to express concerns about the interchangeability of certain products they characterize as narrow therapeutic index (NTI) drug products. A particular concern being raised by them is whether the safety and efficacy profile of these products could change if a switch were made from a brand-name product to a FDA-designated therapeutically equivalent generic product. FDA wishes to comment on the issue of interchanging any brand-name drug with a therapeutically equivalent generic drug and requests that you inform your association's members of this information.

For both brand-name and generic drugs, FDA works with pharmaceutical companies to assure that all drugs marketed in the United States meets specifications for identity, strength, quality, purity and potency. In approving a generic drug product, the FDA requires many rigorous tests and procedures to assure that the generic drug is interchangeable with the brand-name drug under all approved indications and conditions of use. For these reasons, FDA approved-product labeling does not recommend that any additional tests need to be performed by the health care provider when a switch occurs from a brand-name drug product to a generic equivalent drug product, or from one generic equivalent to another when both are deemed equivalent to a brand-name drug product. Brand-name drug products are identified in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, frequently called the *Orange Book*.

In addition to tests performed prior to market entry, FDA regularly assesses the quality of products in the marketplace and thoroughly researches and evaluates reports of alleged drug product inequivalence. To date, there are no documented examples of a generic product manufactured to meet its approved specifications that could not be used interchangeability with the corresponding brand-name drug. Questions have been raised in the past, as well, regarding brand name and generic products about which there could be concern that quality failures might represent a public safety hazard. FDA has performed post-marketing testing on many of these drugs to asses their quality. In one instance, more than 400 samples of 24 marketed brand-name and generic drug products were tested and found to meet the established standards of purity and quality. Because patients may pay closer attention to their symptoms when the substitution of one drug product for another occurs, an increase in symptoms may be reported at that time, and anecdotal reports of decreased efficacy or increased toxicity may result. Upon investigation by FDA, no problems attributed to substitution of one approved drug product for another has occurred.

To date, there are no documented examples of a generic product manufactured to meet its approved specifications that could not be used interchangeably with the corresponding brand-name drug.

FDA works with both brand-name and generic drug product manufacturers after a drug product is in the marketplace to assure its quality. For example, brand-name and generic drug product manufacturers may want to change the drug formulation, site of manufacture or manufacturing process after the drug is in the marketplace. These types of changes can be put in place only after the drug manufacturer provides the FDA with sufficient evidence that the drug identity, strength, quality, purity and potency will not change.

There are products in which small changes in the dose and/or blood concentration could potentially result in clinically important changes in drug efficacy or safety. Usually, these drugs require frequent adjustments in the dose of the drug and careful patient monitoring irrespective of whether the drug is a brand or generic drug product. These drugs may some-

times be described in FDA approved drug labeling as narrow therapeutic range drugs.

FDA may recommend to the manufactures additional test for approval of both brand-name and generic products, depending on the complexity of a drug substance or drug product and also depending on whether small changes in the dose and/or blood concentration could result in changes in drug efficacy or safety. It may also require additional tests for certain post approval changes in manufacturing. The agency's recommendation to the manufacture for these additional tests is designed to give the practitioner and patient additional assurance of product quality and interchangeability. These additional requirements should not be construed to mean that additional clinical scrutiny is necessary when interchange occurs. If anything, the additional tests required of pharmaceutical manufacturers are designed to reduce, not increase, concerns on the part of patients and practitioners.

Based on FDA's determination of therapeutic equivalence between generic and innovator drug products, the FDA concludes that:

♦ Additional clinical tests or examinations by health care providers are not needed when a generic drug product is substituted for the brand-name product.

♦ Special precautions are not needed when a formulation and/or a manufacturing change occurs for a drug product provided that the change is approved according to applicable laws and regulations by the FDA.

♦ As noted in the *Orange Book*, in the judgment of the FDA, products evaluated as therapeutically equivalent can be expected to have equivalent clinical effect whether the product is brand name or generic drug product.

♦ It is not necessary for the health care provider to approach any one therapeutic class of drug products differently from any other class, when there has been a determination of therapeutic equivalence by FDA for the drug products under consideration.

In considering drug product selection decisions, FDA acknowledges and supports the importance of good communication between the patient and the health care provider, particularly with regard to medications that require frequent monitoring of performance. We hope this information is useful to health care providers when making decisions regarding drug product selection.

We thank you for seeing that this information reached the members of your organization.

Sincerely,
Stuart L. Nightingale, M.D. Associate Commissioner for Health Affairs

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EXPLOSIVE NEWS

On February 7, 1998, the North Carolina Pharmacy's Leaders Forum unanimously endorsed the implementation of a single voice for pharmacy by uniting all areas of the profession into one organization working toward the common good of all pharmacists. NCPhA must decide whether to particpate in this process.

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Births

Philadelphia — Fred and Sarah Myatt announce the birth of a son, James Cooper Monroe, born on Feb. 6, 1998, weighing 7 lbs 4 ozs. NCPhA Executive Director **Fred Eckel** and his wife, Peggy, are proud first-time grandparents.

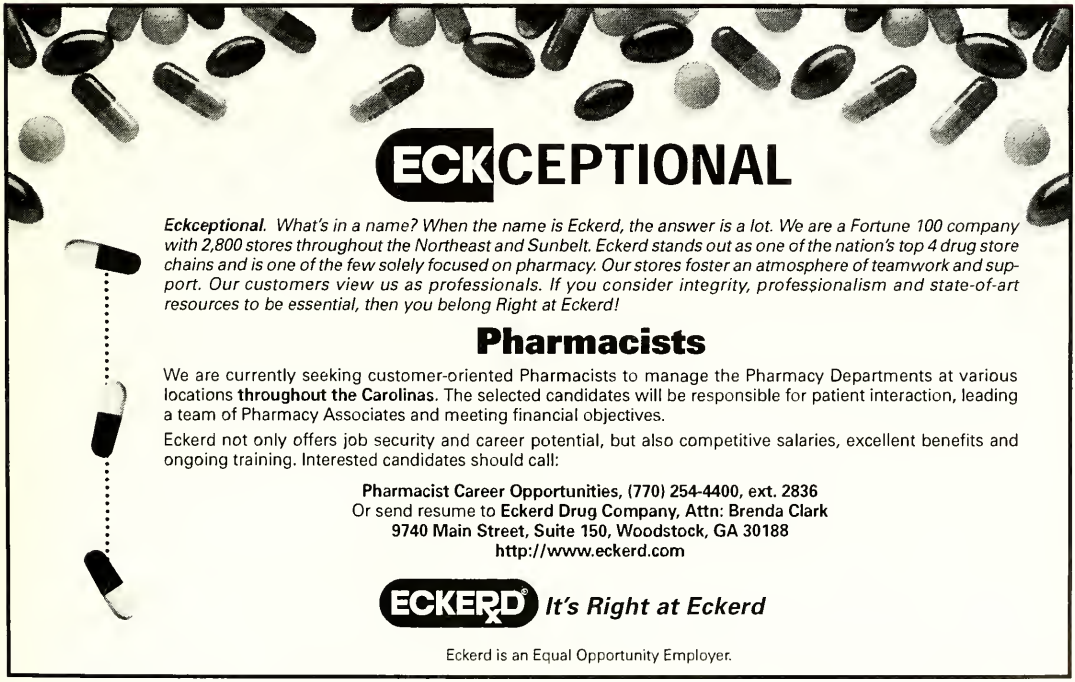
Obituaries

Graham — **Keithan Blanchard "K.B." Jenks**, 67, died Feb. 3, 1998, at Alamance Regional Medical Center. The 1959 UNC School of Pharmacy graduate was part-owner of South Court Drug Store in Graham where he was a pharmacist for 32 years. He was a member of the First United Methodist Church of Graham and a U.S. Army veteran. He is survived by his wife, Peggy Johnson Jenks; daughter, Mrs. Cheryl Potter; son, Rev. Gregory K. Jenks, a sister and two brothers and four grandchildren. He was predeceased by a sister and two brothers. Jenks was born in Richmond County on June 8, 1930, to the late Keither Blanchard Jenks and Annie Harmon Screws.

Charlotte — **William V. Proctor**, 80, died Jan. 24, 1998, at his home in Charlotte. The 1939 UNC School of Pharmacy graduate was born in Denver, N.C. and was raised in Wilson's Mills. He worked for Sterling Drug Store until 1955 when he bought the store and ran it until semi-retirement in 1980. He was inducted into NCPhA's "Fifty Plus" Club in May of 1990. Proctor did volunteer work for the homeless shelter in Charlotte. He was a member of Wilson's Mills Christian Church, and later Charlotte's First United Methodist. He is survived by his wife, Betty Moore Proctor; daughter, Jan P. Granberry; a sister and a brother.

Hendersonville — **Robert Uel Whatley**, 57, of Upson County, Ga., died on Jan. 13, 1998. Whatley graduated from University of Georgia Pharmacy School in 1965 and became a North Carolina resident in 1969. He was the owner of Brevard Pharmacy and Economart Discount Drug Centers in Hendersonville and Etowah. He was a member of NCPhA and a board member of the Western North Carolina Pharmaceutical Association. He was a member of Grace Community Church and is survived by his wife, Becky Whatley; son, Christopher Robert Whatley; a brother, three stepchildren, Amy, Brock and Amber Jackson, and two nephews.

Mount Airy — **Robert Payne Wolfe**, 68, died Jan. 12, 1998, at his home. He became a partner in Square Rexall Pharmacy in 1977 after beginning work at the store in 1963. Wolfe graduated from UNC School of Pharmacy in 1954 and served as a pharmacy consultant with the Surry County Health Department. He was a World War II veteran of the U.S. Air Force. He was an active member of Grace Moravian Church. He is survived by his wife, Phyllis Deane Helms Wolfe, three sons, nine grandchildren, four great-grandchildren, two sisters and two brothers.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1998 N.C. Pharmacy Leaders Forum

The 1998 Pharmacy Leaders Forum met on Feb. 6-7 in Southern Pines to plan the direction of North Carolina pharmacy for the coming year. The main topic on the agenda was consideration of the "One Voice-One Vision for Pharmacy" plan for North Carolina. The Forum heard speakers from other states describe how they embarked on a process to consolidate all pharmacy organizations into a single entity.

Curtis Johnson of Wisconsin described a process that lasted approximately two years and culminated in a new organization, the Pharmacy Society of Wisconsin. This organization is a completely new structure that combines the previous Wisconsin Society of Health-System Pharmacists, the Wisconsin Pharmaceutical Association and other professional organizations. Dr. Johnson identified several critical issues in the process and described how they were handled in the Wisconsin process:

1. The process could either be approached as a "merger" or a creation of an entirely new entity. Due to the complexities of merging by-laws, real estate, financial assets and other resources it was agreed that the term and concept of "merger" would be avoided. An entirely new organization was needed, with an entirely new name and governance structure.

2. The new organization would emphasize common practice interests, and would not be structured to reflect professional practice sites, such as community or hospital pharmacy. The goal was to create an organization to meet the needs of all Wisconsin pharmacists.

3. While affiliation with national organizations such as ASHP and APhA would be desirable and important, such affiliation would not be the primary driving force behind the structure of the new organization.

4. Another key issue was that of cost vs. value. The new organization would have to present a compelling argument that the value of the membership would exceed that of cost in order that the organization be attractive to potential members.

At the culmination of this effort, a vote was conducted, and 98 percent of the voting membership approved creation of the new organization. Effective Jan. 1, 1998, the Pharmacy Society of Wisconsin became a reality, and began operation as a provisionally affiliated organization of ASHP and APhA.

Ms. Janelle Sobotka, Associate Director of the Iowa Pharmacist Association (IPA), described the progress of Iowa pharmacists toward a consolidated structure. Due to the differences in history and relative size of various organizations, it was agreed that a merger approach would better serve Iowa pharmacy. The IPA staff is currently developing by-law revisions, reviewing legal requirements and negotiating policies and procedures for unification of organizations under the IPA banner. It is expected that a vote will be held at the annual meeting of IPA (Summer 1998) to adopt revisions that will allow unification to occur.

The Leaders Forum discussed a "One Voice-One Vision" initiative in North Carolina and noted the number of states (Michigan, Iowa, Wisconsin, Tennessee, Kansas, Hawaii, Indiana) currently pursuing this theme. Fred Eckel recommended that the 1998 Leaders Forum go on record as supporting this initiative and suggested a number of steps that should take place to ensure success. It was moved, seconded and approved by unanimous vote that:

- *North Carolina should move as quickly as possible to establish a single organization representing pharmacy.*

- *The Boards of Directors of North Carolina Society of Health-System Pharmacists, North Carolina Pharmaceutical Association and other organizations as appropriate be urged to convene a joint meeting to address how best to implement "One Voice-One Vision for Pharmacy" in North Carolina.*

- *The executive director position for the North Carolina Pharmaceutical Association, currently vacant, be filled with a person who will be assigned responsibility for implementing a "One Voice-One Vision" initiative.*

- *The Task Force appointed by President Jimmy Jackson will complete its report by submitting recommendations, guidelines and a time-frame for "One Voice-One Vision" initiative in North Carolina.*

Bill Campbell, Ph.D.
Chair, Task Force on
Membership Services

S-U-C-C-E-S-S

Successful was the general word used to describe the 1998 Pharmacy Leaders Forum. Attendees were impressed by the sense of interaction and cooperation at the meeting in Southern Pines.

Much of the success centered on the unanimous vote to consolidate North Carolina pharmacy into one organization working toward the common good of all pharmacists.

"I think this has tremendous opportunity for the pharmacy profession," said Ron Maddox, dean of the Campbell School of Pharmacy. "We get so entrenched in our own turf. We find ourselves diluted. If we speak as one group and work as one group, it will be better."

Tim Giddens, past president of NCSHP, acknowledged that there will be some political stumbling blocks, but he is cautiously optimistic that things can be worked out.

"We need some new formats because our old ones aren't working," Giddens said. "The jury is still out on what model will be best for North Carolina."

Giddens also pointed out that any new organization should try to reach those pharmacists, particularly young ones, that aren't participating in any professional association to see what they want and expect from membership.

Rule changes for N.C. pharmacy

At its January and February meetings, the Board of Pharmacy made decisions on several pending rules proposed for amendment or adoption.

The proposals include:

- An amendment to 21 NCAC 46.1601, Pharmacy Permits, to specify that no more than two unlicensed personnel who spend a majority of their time performing functions constituting dispensing shall be on duty in the pharmacy per pharmacist on duty;
- An amendment to 21 NCAC 46.1603, When Permits Required, to specify when new permits are required;
- An amendment to 21 NCAC 46.1604, Transfer of Permits Allowed, to specify when a permit can be transferred;
- An amendment to 21 NCAC 46.1804, Prescription: Receiving and Dispensing, to prohibit the alteration of prescription orders by a party outside the practitioner-pharmacist-patient relationship and to specify requirements for delivery of prescription orders to a patient off site;
- An amendment to 21 NCAC 46.1810, Compounding, to specify compounding requirements;
- The adoption of 21 NCAC 46.1813, Electronic Transmission of Prescription Orders, to specify requirements for electronically transferred prescription orders;
- An amendment to 21 NCAC 46.2103, Geographic Representations, to require a health care facility pharmacist to be a member of the board and to change geographic representation areas from five to four;
- An amendment to 21 NCAC 46.2201, Hours: Records: Providers: Correspondence: Reciprocity, to specify requirements for an inactive pharmacist;
- An amendment to 21 NCAC 46.2301, Prescription: Drug Order Requirements, to require the indication for the drug prescribed to appear on the prescription order.

by Denise Stanford Haskell

At the January meeting, the Board amended .1603, .1604 and .2201 as noticed. Rule .1810 was amended as noticed with some modifications. The simple reconstitution of drug products was excepted from the compounding log requirements and health care facility pharmacies may comply with certain recordkeeping requirements by merely maintaining records of lot numbers. Rule .1813 was adopted with some changes. The definition of electronic transmission was changed to the transmission of digital representation of the information, and the requirement that there be no additional charge to the patient because the prescription order was electronically transmitted was deleted. These rules were approved by the Rules Review Commission at its February meeting with the exception of .1810. The Commission objected to the rule on the basis that the Board had no statutory authority to regulate advertising. The rule has been returned to the Board for a change to the portion of the rule relating to advertising. If the Board can rewrite the rule to meet the Commission's objection, .1810, as well as the other rules, will become effective on Aug. 1, 1998, assuming no bill specifically disapproving the rule is passed by the General Assembly.

At the February meeting, the Board amended .1601 as noticed. Rule .1804 was amended as noticed with modifications to the originally proposed requirements for off site delivery of prescription orders. The language also was modified to make clear that the delivery requirements apply to deliveries by out-of-state pharmacies and deliveries from one health care facility pharmacy to another or within a health care facility pharmacy were expected from the off site delivery requirements. The Board took no action with regard to Rules .2103 and .2301. Rules .1601 and .1804 will be considered by the Commission at its March meeting. Assuming there is no objection by the Commission and no action taken against these rules by the General Assembly, Rules .1601 and .1804 also will become effective on Aug. 1, 1998.

Denise Stanford Haskell is a partner with the law firm of Bailey & Dixon, LLP in Raleigh. The firm serves as counsel for the North Carolina Board of Pharmacy.

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INSURANCE / FINANCIAL SERVICES

Grants from Knoll Pharmaceutical to go to chemical dependency education programs

David Marley (left), NCPRN executive director, accepts a check from Robert Pearson of Knoll Pharmaceutical Co.

The North Carolina Pharmacist Recovery Network Inc. recently received a $16,000 unrestricted educational grant from Knoll Pharmaceutical Company. Robert Pearson, a government affairs account executive with the company, presented the check to David Marley, executive director of NCPRN, at the January Board of Pharmacy meeting in Chapel Hill.

The money was earmarked for two continuing education programs that address chemical dependency in the pharmacy profession. The first program was held March 14 in Asheville, and the second will be Nov. 15 in Raleigh.

The program in Asheville will focus on the chemically dependent family, while the November program will address women in recovery. (Information regarding these programs can be obtained by calling (336) 774-6555. Brochures will be mailed in advance of the events as well.)

ALCOHOL IMPACT: Families and addicts

by David Marley

Continuing education programs are part of NCPRN's ongoing mission to inform and enlighten pharmacists and pharmacy students about the disease of addiction. This issue has such far reaching ramifications that it is the responsibility of every professional to view it in the context of being a serious illness, rather than a moral weakness.

Some argue that the impaired individual has "done this to himself or herself" and is therefore undeserving of any form of compassionate treatment. However, one must consider the spouse or the children that are affected. Have they done this to themselves as well?

Living in a home with an addict or alcoholic can be described as nothing short of a living hell. Emotional damage done to a child can continue long into adulthood with the trauma manifesting itself in a variety of dysfunctional behaviors. Support groups for Adult Child of an Alcoholic/Addict (ACOA) exist for the now grown-up children who lived in an alcoholic environment.

It is said that an impaired individual has a direct impact on ten people around them. That means that if there are 10 percent, or 650 pharmacists, practicing while impaired, then they have a direct negative impact on 6,500 family members, friends, clients and colleagues.

While it is possible to treat the family members regardless of whether the individual gets sober, it is much easier to stop the process by intervening in the life of a chemically dependent person, and to allow the individual and family to seek treatment together.

We know that toddlers and young children are much smarter than we often give them credit. We also know that children mimic what they see their parents doing. If the impaired individual is allowed to progress in his disease, in many cases, the children will follow suit.

Whatever you choose to call it, nature or nurture, genetics or bad parenting, we have a responsibility to the children, if not the colleague, to step in and help. While one may appear to have it together at work, the damage is still being done to the family at home.

In many cases, the job is the last thing to go. This only feeds into the impaired person's sense of denial. How often have you heard someone say, "I don't have a problem. If I did I would have lost my license by now." Maintaining the job allows the person to continue to fool himself and those around him into feeling he is still in control.

It has long been said that the individual is not responsible for having this disease. They are, however, very much responsible for treating it. Unfortunately the individual, and historically, we as a profession, are too much in denial to see it.

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The HIV family tree: Finding the origin of AIDS

A team led by David Ho, director of the Aaron Diamond AIDS Research Center in New York City, published the first solid evidence to support the notion that HIV-1 — the version of the AIDS virus that causes most cases of the disease in the world — was lurking in the human population by the 1950s. A recent issue of *Nature* reports that it has fished out and sequenced fragments of an early HIV-1 genome from a 1959 blood plasma sample. The sample came from a man living in what was then Leopold, Belgian Congo, and what is now Kinshasa, capital of the Democratic Republic of the Congo. It was originally collected as part of a study of immune system genetics. If the results prove correct, this would be the earliest confirmed case of HIV infection.

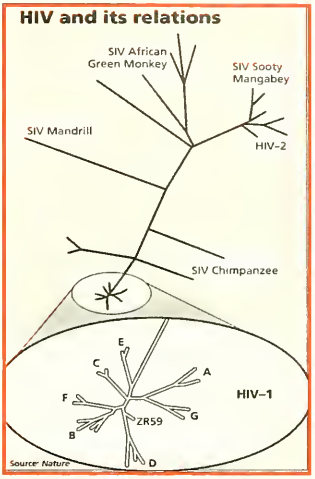
In 1986, Andre Nahmias, a virologist at Emory University School of Medicine in Atlanta and a co-author of the new study, screened some 1,200 plasma samples from various parts of Africa that had been stored away for years in a freezer after undergoing human genetics testing. One sample, dating from 1959, tested positive for anti-HIV antibodies. After numerous attempts to detect HIV genes using the polymerase chain reaction, Tuofu Zhu, a postdoc in Ho's lab, was able to squeeze out four small fragments representing less than 15 percent of HIV's genome.

These fragments were sequenced and sent to Bette Korber of the Los Alamos National Laboratory in New Mexico and Paul Sharp at the University of Nottingham in the United Kingdom, both experts in deriving HIV phylogenies. Each determined independently that the 1959 strain, dubbed ZR59 (after Zaire, the name by which the Congo was known when AIDS was discovered), evolved soon after the common ancestor of three common HIV-1 subtypes known as B, D and E.

The results confirm the prevailing scientific consensus that HIV is a virus that crossed over the "species barrier" and into mankind. But they suggest that the hop took place longer ago than had been suspected. They also suggest that, at least for the form of AIDS which is now spreading worldwide, this hop took place only once which means there was a true "patient zero." He was not, however, the world's notorious airline steward, but rather an anonymous African who somehow and in some manner that will probably remain a mystery, tangled with a chimpanzee and came away with more than he bargained for.

The origin of a species

Simply put, viruses are packets of genetic material, generally DNA which carries genes in plants, animals and bacteria, which are usually wrapped in a protein coat. HIV is an exception because it is in an aberrant class of virus known as retroviruses, which package their genes in the form of RNA. DNA's sister molecule. A reading of the genetic "letters" found on either RNA or DNA which carry the information needed to build new viruses allows a family tree to be constructed. The more similar the sequences of genetic letters in two viruses, the more recently they diverged from a common ancestor.



While examining the HIV tree, it became apparent early on that there are two different forms of AIDS, caused by two different (though related) viruses. These are now known as HIV-1 and HIV-2. The global AIDS epidemic is caused by HIV-1, and HIV-2 is more or less confined to West Africa.

HIV-1 is a fast-moving virus. Plotting its recent history reveals what evolutionists refer to as a "starburst." The seven different strains of the virus diverge rapidly from their putative point of origin and continue to divide into sub-strains. By looking at the rate of diversification, geneticists can make a guess about how long ago all AIDS strains were the same. The original date was thought to be the late 1950s or early 1960s, but Dr. Nahmias's sample pushes this date back somewhat. When it is plotted on to the starburst, ZR59 sits gratifyingly close to the middle, near the common an-

cestors of strains B, D and E, but not quite at the point of origin. Strains A, C, E and G had closely branched off already. That suggests the common ancestor of the whole cluster had existed about a decade earlier, in the late 1940s or early 1950s. And, by finding a human virus so close to the cluster's point of origin, Dr. Ho and his colleagues have more or less confirmed that HIV-1 leapt the species barrier only once.

This is where the chimp comes in because HIV-1's family tree can be traced back further still. Chimpanzees (and also many species of monkey) sometimes carry viruses called SIV (simian immunodeficiency viruses). Most of these viruses are harmless in their natural hosts, though they may become virulent (causing symptoms identical to AIDS) if introduced into other species of monkey. In fact, SIVS are so similar to HIV that if virologists were not antropocentric in their classifications, HIV would probably be thought of as just another sort of SIV.

Comparing the genetic sequence of HIV-1 with the various SIVS suggest that it evolved from a SIV found in chimpanzees. (HIV-2 seems to have evolved from the SIV of the sooty mangabey monkey.) If the various HIV-1 strains had separated in chimpanzees before they leapt into people, then even an early sample such as ZR59 would have been further along one of the branches seen today.

By placing ZR59 so close to the original case of HIV-1 infection, Dr. Ho's work also helps confirm where AIDS started (those who study SIVS have long suspected the eastern Congo as the place where the first human infection happened) and also why it has become so widespread. Many simian viruses (Marburg fever, Lassa fever and Ebola fever, to name a few) are able to thrive in people, to the fatal detriment of their hosts, yet none of these have reached epidemic proportions. Partly, this is because they kill quickly, while AIDS kills slowly and thus has time to spread. But it is also likely that AIDS was kick-started by human behavior.

Around a year after ZR59 was collected, the Congo erupted into one of the bloodiest and most disruptive civil wars in African history. War, and the refugees and starvation which result from it, provide ideal circumstances for any disease to spread, and the activities of armies composed largely of young men are particularly likely to give a sexually transmitted infection a boost. Without the Congolese war, HIV-1 might still be confined to a small area of Africa like its cousin HIV-2.

A better understanding of HIV's origins may boost efforts to develop an AIDS vaccine, which are currently hampered by the genetic diversity of different strains, whose sequences can vary from each other by 10 percent or more. Knowing more about the common ancestor of these strains might help pinpoint those segments of HIV's genome that have changed the least over time, which could then become vaccine targets. Also, a vaccine based on common features shared with HIV's early ancestors may prove to be more universal in fighting the global epidemic than vaccines based on combining a cocktail of modern subtypes.

Based on articles appearing in ***The Economist*** *(Feb. 7, 1998) and* ***Science Magazine*** *(Feb. 6, 1998, Michael Balter)*

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Medicare surety bonds

Your help is needed. Sen. Byron Dorgan (D-ND) introduced S.1680, legislation that will exempt licensed pharmacists from the Medicare surety bond requirement imposed by the Balanced Budget Act of 1997. Similar legislation will likely be introduced in the House by Rep. Berry (AK). NCPA and APhA are both fully supporting this legislation.

The bill has been assigned to Senate Finance Committee. There is a chance of it being added to the technical corrections bill to the Balanced Budget Act of 1997 with a vote on the technical amendments prior to Easter. If that is true, and this effort is successful, there is the chance that pharmacies could be exempted from the Surety Bond requirement before HCFA formulates its final rules. In developing the Surety Bond rules, HCFA estimated that the $50,000 Surety Bond would cost $778.00. This may save the 35,000 pharmacies across the country represented by NCPA over $27 million each year and enable many pharmacists to continue serving their Medicare customers.

Contact your senators and representatives and ask them to consider supporting this action.

You can find full comments about the bill in the Feb. 25 Congressional Record on pages S1012-S1014 and H614. These can be accessed through the Internet on Thomas at **http://thomas.loc.gov/**.

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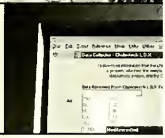

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Patient Counseling: New Anti-HIV Drugs of 1997; Part 1: Therapy of AIDS

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Goals. The goals of this two-part series are to discuss new antiretroviral drugs, current concepts in the therapy of AIDS, and publications of the National Institutes of Health (NIH) and the U.S. Department of Health and Human Services (DHHS) released during 1997. The benefits of combination therapy with antiretroviral drugs, their mechanism of action and the need for strict compliance with therapeutic regimens will be presented.

Objectives. At the conclusion of this lesson, the participant should be able to:

1. select the correct information about current concepts in the treatment of HIV infections;
2. choose appropriate information about the pharmacology of antiretroviral drugs; and,
3. demonstrate an understanding of important information to convey to patients receiving antiretroviral drugs.

A professional development program made possible by an educational grant from

SEARLE

Gossel

Wuest

Two new drugs for treating HIV infections were approved by FDA in 1997: nelfinavir [nel-FIN-a-veer] (Viracept) [VEER-a-sept], a protease inhibitor, and delavirdine [dela-VEER-dean] (Rescriptor) [Ree-SKRIPT-oar], a non-nucleoside reverse transcriptase inhibitor. This brings the number of antiretroviral drugs on the market to eleven.

Antiretroviral drugs refer to those which are capable of inhibiting replication of the retrovirus HIV (human immunodeficiency virus). HIV is a member of the family of viruses called *Retroviridae*, which contains reverse transcriptase, the enzyme that converts RNA to DNA to begin the process of viral replication. It also contains a protease enzyme whose function will be discussed shortly. HIV is the transmissible virus that causes acquired immunodeficiency syndrome (AIDS).

HIV depresses cell-mediated immunity in humans resulting in an increased occurrence of infections by organisms (bacteria, protozoa, fungi, viruses) that are not normally pathogenic, or to which humans have natural immunity (opportunistic organisms). Patients with AIDS also have a higher than normal occurrence of cancer (especially Kaposi's sarcoma) and lymphomas.

The drugs currently approved for treating HIV infections are classed into three categories: nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors and protease inhibitors.

Nucleoside reverse transcriptase inhibitors are nitrogen-containing compounds that closely resemble one of the building blocks of DNA/RNA. For example, the first available antiretroviral drug, zidovudine (Retrovir), is similar to the nucleoside thymine, except that it contains an unreactive moiety that will not allow linkage of the next nucleotide in the HIV DNA chain.

These drugs block viral replication. They inhibit elongation of the viral DNA chain before it is inserted into the human host cell's genome. A genome is the complete strand of DNA that allows an organism to replicate itself. In humans, our genome is very complicated in that it contains all of our chromosomes which contain all of our genes which contain all of our DNA strands. Pathogenic viruses have the capacity to incorporate their very simplistic genome into ours, take over the genetic coding of the infected host cell and replicate themselves. Antiretroviral drugs inhibit the ability of HIV to do this.

Until several years ago, the nucleoside reverse transcriptase inhibitors were all that was available. In reality, they provided only modest improvement in patient survival. While they do delay progression of AIDS symptoms, they have no effect on cells in which the viral genome has already been incorporated into the host's genome. Another drawback is that resistance develops, and they can produce significant adverse reactions such as bone marrow depression and neuropathies.

The second type of antiretroviral drug to be approved is the **protease inhibitors**. Because of problems seen with the nucleoside reverse transcriptase inhibitors, intense research was undertaken to develop anti-HIV

Table 1
Antiretroviral Drugs Currently on the Market

Generic Name	*Trade Name*	*Availability*
1. Nucleoside Reverse Transcriptase Inhibitors		
Didanosine	Videx	tablet, powder (capsule soon)
Lamivudine	Epivir	tablet, oral solution
Stavudine	Zerit	capsule, powder for oral solution
Zalcitabine	Hivid	tablet
Zidovudine	Retrovir	capsule, tablet, syrup, injection
2. Non-Nucleoside Reverse Transcriptase Inhibitors		
Delavirdine	Rescriptor	tablet
Nevirapine	Viramune	tablet
3. Protease Inhibitors		
Indinavir	Crixivan	capsule
Nelfinavir	Viracept	tablet, powder
Ritonavir	Norvir	capsule, oral solution
Saquinavir	Invirase	capsule (scheduled to be replaced in early 1998 by a more bioavailable capsule under the name Fortovase.)

drugs with different mechanisms of action. The protease inhibitors resulted from this research. They suppress viral replication after DNA has been incorporated into the human genome. Protease cleaves viral precursor polypeptides into infective virions.

Unlike nucleoside reverse transcriptase inhibitors, protease inhibitors do not require bioactivation in the host cell. Therefore, they are active even in cells that are not replicating. They are synergistic to the nucleoside reverse transcriptase inhibitors and represent a major advance in the treatment of HIV infection. To shed light on their importance, one of these drugs, indinavir (Crixivan), was approved in approximately 40 days rather than requiring the many years normally involved in new drug approvals.

The third type of antiretroviral drug approved by FDA, in 1996, is in the **non-nucleoside reverse transcriptase inhibitor** class. These agents inhibit the activity of reverse transcriptase in a manner independent of nucleoside linkage. While the nucleoside reverse transcriptase inhibitors compete with the linking of HIV DNA components to polymerize them into their progeny, these drugs bind directly to reverse transcriptase and disrupt its catalytic activity. This may be difficult to comprehend without a full review of virology and human genetics, but the net result is a synergistic activity that exceeds that of either type of drug alone.

The good news is that concomitant use of all three types of drugs has led to the lowering of viral load below measurable levels. In some patients, this has continued since therapy with these combination "cocktails" was initiated more than two years ago. For a time, it was felt that the combined use of several, or all three types of drugs, could provide significant suppression of HIV activity if not complete eradication. Results look promising, but unfortunately, undertreatment by physicians and lack of compliance by patients has lessened these amazing results in some patients. Proper therapy may entail 40-50 doses of drugs at unusual intervals during the day, some requiring administration with food and others on an empty stomach.

The commercially available antiretroviral drugs are listed in Table 1.

It is noteworthy that two very important documents related to the treatment of HIV infections were published in 1997. These are the *Report of the NIH Panel to Define Principles of Therapy for HIV Infections*, and the *Guidelines for the Use of Antiretroviral Agents in HIV-infected Adults and Adolescents*.

These publications are important because their major concepts lead the way for improved quality of care for HIV-infected patients. The Panel Report was prepared by the National Institutes of Health (NIH) and the "Guidelines" were formulated by a panel working with the U.S. Department of Health and Human Services (DHHS). Currently in pre-approved drafts, they are available from the CDC National AIDS Clearinghouse (1.800.458.5231).

Report of the NIH Panel to Define Principles of Therapy for HIV Infections

The stated goal of the NIH Panel report was to review the dramatic advances in both basic and clinical research on AIDS that had occurred the previous year. The Panel stated that, "The availability of more numerous and more potent drugs to inhibit HIV replication has permitted the design of therapeutic strategies involving combinations of antiretroviral drugs that accomplish prolonged and near complete suppression of detectable HIV replication in many HIV-infected patients." However, early success in eradicating plasma levels of HIV virions in infected patients has been dulled by their reappearance in patients who were undertreated by their physician or noncompliant (e.g., unwilling to take the large number of daily doses of antiretroviral drugs needed in combination therapy).

This led NIH and its Panel to develop specific guidelines to assist physicians and other health care providers in making more informed decisions about treatment options and helping them treat HIV-infected patients properly, as well as maximizing patient compliance. The major findings of the Panel are:

1. To be effective, antiretroviral therapy must be introduced before extensive damage to the patient's immune system has occurred.

2. Viral load (amount of viral particles in plasma) monitoring should be used to determine an HIV-infected patient's response to therapy.

3. Combination antiretroviral therapy should be used in high enough doses to suppress HIV replication.

4. Patient adherence to the complicated regimen of combination therapy is required for success.

Pharmacists can help in attaining the therapeutic goals by assuring that doses are prescribed in recommended rather than subtherapeutic quantities. Undertreatment leads to viral resistance and decreases the likelihood of patient survival. Assistance can be provided by convincing HIV-infected patients to fully comply with their therapy, even though it is complicated and burdensome. It has already been demonstrated that noncompliance reverses the dramatic lowering of viral load and increased survival rates initially seen with combination therapy, due to the development of drug-resistant viral strains. Sadly, it appears that once drug-resistant viruses occur, the prospect of any currently available drug regimen being effective is lessened.

Another finding of the Panel was, "In the absence of effective inhibition of HIV replication by antiretroviral therapy, nearly all infected persons will suffer progressive deterioration of immune function resulting in their susceptibility to opportunistic infections, malignancies, disease and wasting, ultimately leading to death."

The major obstacle to the long-term efficacy of antiretroviral therapy is the inherent ability of HIV to develop drug resistance. No single antiretroviral drug provides significant, lasting suppression of HIV replication when used alone. This fact supports the concept of combination therapy, which can delay and possibly prevent the development of resistance. It has been shown that stopping HIV replication decreases mutation that leads to drug-resistant strains of viruses.

The efficacy of combination antiretroviral therapy is not a simple function of the number of drugs used. The drugs should demonstrate synergism, not affect each other's kinetics or antiretroviral activity, and should not cause similar toxicities. When combination therapy is initiated, all drugs should be started simultaneously, preferably at the same time but at least within one to two days of each other. Adding the drugs sequentially decreases the likelihood of complete suppression of HIV replication. The Panel stated that, "Rather than strive to increase patient acceptance of therapy through sequential addition of antiretroviral drugs . . . it is better to counsel and educate patients extensively before the initiation of antiretroviral therapy, even if it means a limited delay in initiating treatment" (until they can be convinced to follow the drug regimen).

Table 2
Factors to Consider in Treating an Asymptomatic HIV-Infected Patient*

Factors Favoring Treatment
- Potential for maximally suppressing viral replication
- Preserving immune function
- Prolonging health and life
- Decreasing drug resistance risk due to early suppression of viral replication
- Lessening toxicity since the patient is healthier

Factors Against Treatment
- Adverse drug effects
- Decreased quality of life
- Inconvenience of complicated therapy
- Potential for developing drug resistance despite early therapy
- Limitation of future treatment options with early therapy
- Risk of transmission of viruses resistant to protease inhibitors
- Unknown effectiveness of long term therapy
- Unknown toxicity associated with long term therapy

Associated Factors
- Patient's willingness to begin therapy
- Degree of existing immunodeficiency
- Risk of disease progression from current level of immunodeficiency
- Likelihood of patient compliance

*From *Guidelines for the Use of Antiretroviral Agents in HIV Infected Adults and Adolescents.* Full report available from CDC National AIDS Clearinghouse (1.800.458.5231)

Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents

Adult HIV-infected patients are divided into three major categories when determining what type of therapy to initiate: patients who are HIV positive but show no clinical symptoms; patients who are symptomatic; and pregnant patients. With the latter, the decision on whether to treat or not depends on many factors including the trimester in which the condition was diagnosed and how far the disease has advanced. This decision is very complicated and beyond the scope of this lesson.

Table 3
Preferred Antiretroviral Combination Therapies for Treating Established HIV Infection*

Protease Inhibitor	Nucleoside Reverse Transcriptase Inhibitor
Indinavir (Crixivan)	Didanosine (Videx) + Zidovudine (Retrovir)
Nelfinavir (Viracept)	Didanosine (Videx) + Stavudine (Zerit)
Ritonavir (Norvir)	Zalcitabine (Hivid) + Zidovudine (Retrovir)
Ritonavir (Norvir) + Saquinavir (Invirase)	Lamivudine (Epivir) + Zidovudine (Retrovir)
Ritonavir (Norvir) + Saquinavir (Invirase)	Lamivudine (Epivir) + Stavudine (Zerit)

*Opinion of DHHS Panel

Treatment of Asymptomatic Patients

While it has been shown that therapy with antiretroviral agents can be of benefit to patients in advanced stages of HIV infection, it has yet to be proven that there are long term benefits in asymptomatic patients. The Panel reported that an estimated 50 to 90 percent of patients acutely infected with HIV will experience at least some symptoms of the acute retroviral syndrome. Some will advance to full blown AIDS. Clinical studies to date are inconclusive because they have had small numbers of patients, short duration of follow up and often involved suboptimal doses (based on what is known today) of antiretroviral drugs. Nevertheless, the report concluded that the information available generally supports antiretroviral treatment of acute HIV infection.

The Panel commented that a major dilemma in deciding whether or not to treat these patients is that therapy is complicated, the drugs have undesirable side effects and drug interactions, and compliance is difficult. There is a definite benefit-to-risk decision to make. Factors that are taken into consideration are listed in Table 2.

Paramount in the decision to use combination therapy is the ability of the patient to understand the need for strict compliance and willingness to comply. Intensive patient education and follow up is needed. Pharmacists should monitor refill intervals, provide positive support to compliant patients and inform physicians when there is evidence of noncompliance. As stated earlier, undertreatment and noncompliance increase the risk of drug resistance. Once resistant viruses develop in a patient, the likelihood of therapeutic success with that combination of drugs or similarly acting ones diminishes.

Once the decision is made to treat an asymptomatic patient, therapy should be as aggressive as in patients in advanced stages of the disease. The goal is to suppress plasma viral load to undetectable levels.

Treatment of Patients with Advanced Disease

There is no doubt that patients who are diagnosed after they are in advanced stages of HIV disease (i.e., have developed opportunistic infections, malignancies, wasting and/or dementia) should be treated aggressively. Certainly, the severity of illness, ability to comply with therapy and laboratory abnormalities must be taken into account, but the benefits of therapy usually outweigh the risks.

The dominant viewpoint on how to maximally suppress HIV viral load is a three drug regimen utilizing one protease inhibitor and two nucleoside reverse transcriptase inhibitors. Combinations preferred by the DHHS Panel that developed the "Guidelines for Therapy" are listed in Table 3. There are many other combination regimens that have and are being studied, but the list represents the Panel's opinion of those with the strongest evidence of effectiveness to date.

When choosing the best regimen for a given patient, consideration must be given to the existence of overlapping drug toxicities and interactions with other drugs being used to treat opportunistic infections. For example, some protease inhibitors cause hepatotoxicity which can be troublesome to patients with underlying liver dysfunction. Zidovudine suppresses bone marrow activity, while didanosine, stavudine and zalcitabine can cause neuropathic effects. Used together, the combined effects may be intolerable to some patients.

Part 2 will present information on the mechanisms of action, drug interactions and patient counseling for the newly approved antiretroviral drugs.

NCPhA Annual Convention

Omni Europa Hotel
Chapel Hill, NC
May 28-31, 1998

Continuing Education Quiz

Patient Counseling: New Anti-HIV Drugs of 1997; Part 1: Therapy of AIDS

1. A drug that inhibits elongation of the HIV DNA chain before it is inserted into the human genome is a:
   a. deoxyribonuclease inhibitor.
   b. nucleoside reverse transcriptase inhibitor.
   c. protease inhibitor.
   d. non-nucleoside reverse transcriptase inhibitor.

2. Which of the following is a protease inhibitor?
   a. Nevirapine
   b. Stavudine
   c. Indinavir
   d. Zidovudine

3. Zidovudine most closely resembles which of the following nucleosides?
   a. Adenine
   b. Cytosine
   c. Guanine
   d. Thymine

4. An accurate statement concerning NIH Panel's Principles of Therapy for HIV infections is:
   a. patient adherence to the complicated regimen of combination therapy is required for success.
   b. antiretroviral therapy is most effective if it is introduced after immune system damage occurred.
   c. combined antiretroviral therapy should be at dosages low enough to avoid adverse effects.
   d. Plasma drug levels are the best method for monitoring patient response.

5. Most experts agree that the best way to maximally suppress viral load is to use:
   a. three nucleoside reverse transcriptase inhibitors.
   b. two nucleoside reverse transcriptase inhibitors and one protease inhibitor.
   c. two protease inhibitors and one nucleoside reverse transcriptase inhibitor.
   d. three protease inhibitors.

6. A drug that suppresses viral replication after the HIV DNA has been incorporated into the human genome is a:
   a. deoxyribonuclease inhibitor.
   b. nucleoside reverse transcriptase inhibitor.
   c. protease inhibitor.
   d. non-nucleoside reverse transcriptase inhibitor.

7. Which of the following is a nucleoside reverse transcriptase inhibitor?
   a. Lamivudine
   b. Nelfinavir
   c. Ritonavir
   d. Saquinavir

8. All of the following are true EXCEPT:
   a. combination therapy can delay and possibly prevent the development of viral resistance.
   b. when combination therapy is used, at least one month should elapse between starting each drug.
   c. patients should be convinced to fully comply with combination antiretroviral therapy even though it is complicated and burdensome.
   d. undertreatment of HIV infection leads to viral resistance and decreases the likelihood of patient survival.

9. All of the following pharmacist interventions in HIV infection therapy are appropriate EXCEPT:
   a. monitoring refill intervals.
   b. providing support to compliant patients.
   c. instructing patients to take a one-week drug-free holiday every 90 days.
   d. informing physicians of noncompliance.

10. The goal of therapy for HIV infection is to:
   a. use the fewest number of drugs simultaneously.
   b. suppress plasma viral load to undetectable levels.

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CORRECTION

CORRECTION: The Carolina Journal of Pharmacy incorrectly credited the article "Changes in Community Pharmacy" (May/June 1996) to Lisa Ezelle. Dawn Jennings was the author. We apologize for error and the delay in the correction.

Must See NPTV!

Gary Glisson of Ward Drug Store in Nashville, NC, invites pharmacists interested in the new direct-broadcast satellite technology to stop by for a first-hand view of how this in-store television system works and what it can do for you.

For details, call NCPhA at (919) 967-2237 or 1-800-852-7343

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- Diagnosis codes were added to the patient record.
- The ability to build sigs from partial sigs and whole words intermixed was added.
- Security measures were added to prevent charging to unauthorized customers.
- Multiple third parties may be added to the customer record and the primary third party serves as the default. Secondary third parties may be billed in batch or individually by indicating the prescription numbers and dates.

  When billing a second third party such as Medicaid, you may indicate what the other payor amount was. The new rebilling function makes retroactive Medicaid billing a cinch.
- The entire MediSpan drug file (total file) was added. This file is updated and added to each week. You can add new drugs to your system drug file anytime you wish, even during a refill, by typing in the new NDC and the drug will be instantly pulled from the total file.
- Multiple user-defined tax rates were added.
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Fred Eckel, MS
Executive Director

Musings from the Hill

What's a pharmacist to do? Nutriceuticals, herbals and other natural products are a huge market. However, these products often are untested in a scientific manner, unregulated as to purity and safety, and frequently promoted inappropriately. Calling these products alternative medicines implies that they are used instead of allopathic products. I like the British term "complementary medicine" because it implies that these products are used to complement the more common drug therapy of the day. Many allopathic drug products are used for unapproved uses. The diet drug combination "Phen Fen" was a widely used therapy that was unapproved. Is this situation any different than selling "shark cartilage" for cancer prevention? When you fill a prescription for an unapproved use, are the legal or ethical issues different than when you sell glucosamine? Some believe (and I am one of them) that dispensing allopathic drugs for unapproved uses or selling nutriceuticals, etc. in a pharmacy allows the pharmacist to provide education. Therefore, pharmacists need to be knowledgeable about alternative products.

I believe it is appropriate for pharmacists to handle these products, although, as you will see in this issue, some do not agree with me. I am becoming more concerned that paternalism continues to be a dominate attitude by some professionals who seem to believe that they know best what a patient needs. Should patients have the right to make mistakes, too? I think they should, provided that they have the information they need to make an informed choice. That is why I favor providing these products in pharmacies so a professional information source is available. That means that pharmacists will need to become better informed to serve in this role. Donna Lee, of Natural Alternatives in Greensboro, shares sources in this issue that she used to accomplished this acquisition of new knowledge. Is this a market you need to explore? Perhaps speaking to someone like Donna Lee will be helpful if you decide to pursue this.

Let me now address some NCPhA issues. Currently our membership is at 1,500 — which represents a drop of over 1,000 members in the last 5 years. Is NCPhA an organization worth reviving? I believe that it is, but we need your support and membership. A membership promotion is being undertaken. Join now for the rest of 1998 for $60, or pay the $135 yearly rate and get your membership extended through the end of 1999. We also are asking 39 life members to step up and match the $1,000 challenge of an anonymous donor to help eliminate the $40,000 loss which occurred in 1996. Can we count on your support? Your tax deductible donation can be made to the NCPhA Endowment Fund.

This is the last issue that will be published during my tenure as acting executive director. During June, Dan Garrett will join NCPhA as executive director. We will work together during the month to try to accomplish a smooth transition. Then in July, I will return to the UNC School of Pharmacy.

Until you sit in the executive director's chair, you cannot really appreciate the importance of the position. Often we take NCPhA, its staff and its activities for granted. You have a staff that is trying hard to strengthen your organization. The influence that can be exerted by NCPhA is tremendous. (This was the major revelation that came from serving as executive director.) A strong organization is necessary to do this well. We need everyone's commitment to bring NCPhA or its subsequent organization back to financial security, organizational efficiency and membership growth. Those past pharmacists who gave us a strong foundation expect nothing less than our best effort. Can we count on you?

Fred blows out the candles at his surprise birthday party given by the NCPhA staff. He is wishing for a day off to go to the next NASCAR race.

New Executive Director for NCPhA

The North Carolina Pharmaceutical Association is prepared to enter into the 21st century with a new and capable leader to head the charge. The Executive Committee has announced that Daniel Garrett will be the new Executive Director of NCPhA by July 1. In this new position, Garrett hopes to carry out the mission of NCPhA *to unite, serve and advance* the profession of pharmacy. He also looks forward to talking to the members of the Association on a grassroots level because as Garrett learned in his early days working in the Dow Chemical lab, "Molecules don't talk, people do."

Garrett is very enthusiastic and well-prepared for the challenge. After serving for 10 years as the director of pharmacy and team leader for adult medicine at Memorial Mission Medical Center in Asheville, he took over in 1996 as director of pharmacy for the combined Mission St. Joseph's Health System. The system includes three hospitals, two outpatient pharmacies and four extended-care facilities.

NCPhA President Jimmy Jackson feels very confident about the job Garrett will do. "There have been many changes in the pharmacy profession, both economically with third party payers and educationally with the switch to PharmD programs. We needed someone who could deal with these changes, and someone who had experience working with large numbers of people," said Jackson. "He brings all of these special skills to the job."

Using a servant leadership style and putting into place self-managed work teams, Garrett has been able to successfully merge two culturally-rich and historic hospitals into one system and help to facilitate the Asheville Project through the North Carolina Center for Pharmaceutical Care.

He plans to use these same techniques to unify the many pharmacist groups into one working organization. He has formulated a plan as to how NCPhA can help the 6,700 pharmacists in North Carolina better serve their patients based on his experiences and the thoughts and ideas of people he has met.

"Organizational development and growth is dependent on the development and growth of individuals," said Garrett, who holds a MS in Administration from Central Michigan University. "The role of the leader is to identify and connect the talents of people who have common goals."

Garrett believes that the first and most critical step to revitalization and preparation for the next millennium is to restore the spirit of the Association.

"Spirit is present in every pharmacist, and we need to listen to pharmacists around the state in all practice settings and then begin the process of connecting practitioners around their common interests," said Garrett.

He has hopes that this renewed spark and fervor for a professional association that supports all pharmacists will increase membership, leadership, productivity, financial support and legislative clout. Garrett wants people to see that "NCPhA represents the door to pharmacy's future for all pharmacists."

Interim Executive Director Fred Eckel has spent his time at NCPhA working towards the same goal. He feels that Garrett will follow through on the proposed changes.

"His leadership abilities will ensure a bright future for North Carolina pharmacy," said Eckel. "I know he is committed to pursuing an 'One Voice-One Vision' organizational structure for pharmacy which I believe is necessary for the profession to achieve its full potential."

Garrett has been active with both professional and community activities. He helped efforts to create NCCPC and has served in numerous capacities as a member of North Carolina Society of Health-System Pharmacists. His self-proclaimed hardest job ever was serving as commissioner of the Hominy Valley Girls Softball Youth League.

Garrett is originally from Saginaw, Mich. He received a BS in pharmacy from Ferris State College and has worked in both hospital and retail pharmacy. He moved to the South in 1981 and currently resides in Greensboro. His wife, Anna, is a pharmacist, and they have three children, Stephanie, 20, Jennifer, 18, and Caroline, 10.

NCCPC and the Asheville Project

The North Carolina Center for Pharmaceutical Care (NCCPC) is a coalition of academic and professional practice organizations whose primary mission is to promote pharmacists as providers of pharmaceutical care. It grew out of a joint committee formed in 1994 by the North Carolina Society of Health-System Pharmacists and the North Carolina Pharmaceutical Association. The task was to design and implement a research project to investigate how pharmaceutical care should be approached in the state. As funding was obtained, and the need for staff support became apparent, the groups recommended a formal organization be formed. NCCPC was established in the Fall 1996, and non-profit corporation status was sought.

NCCPC, teamed with Mission St. Joseph's in Asheville, began coordinating and funding a study known as the Asheville Project in early 1997. It was to be a year-long demonstration project to determine pharmacists' impact on disease management in patients with diabetes. Fifty employees of the City of Asheville with diabetes were seen by 24 trained community pharmacists. After only three months, feedback from employees was so favorable that the City began compensating the pharmacists for their time rather than waiting until outcomes were reviewed at the end of the program.

Phase I was so successful that an additional year-long pilot to determine pharmacists' impact on disease management of patients who have asthma was started in November 1997. Employees of the City of Asheville and Mission St. Joseph's with asthma were enrolled in a study modeled on the diabetes program.

For more information call, NCCPC at (919) 933-9709.

...O, mickle is the powerful grace that lies
In herbs, plants, stones and their true qualities:
For nought so vile that on the earth doth live
But to the earth some special good doth give,
Nor aught so good but strain'd from that fair use
Revolts from true birth, stumbling on abuse:
Virtue itself turns vice being misapplied,
And vice sometimes by action dignified.
Within the infant rind of this small flower
Poison hath residence and medicine power:
For this, being smelt, with that part cheers each part,
Being tasted, slays all senses with the heart.
Two such opposed kings encamp them still
In man as well as herbs grace and rude will;
And where the worser is predominant,
Full soon the canker death eats up that plan.

Romeo & Juliet
Friar Laurence - Act II Scene III
~ William Shakespeare ~

by Jennifer Olivia Windley

Even good old Shakespeare had a thing for herbs, and so does an estimated 30 percent of adults in the United States according to a 1997 Gallup survey. Some studies report that approximately $2 billion was shelled out for medicinal herbs in capsules, tablets, extracts, bulk herbs and teas in 1997 — nearly double the amount from four years ago. You may think that consumers are buying from every side street herbal specialty shop and health-food store in the country, but an increasing number of Americans are actually visiting their neighborhood pharmacist to obtain vitamins, herbs and homeopathic products. Almost $53 million worth of herbs are sold in pharmacies each year.

Natural products are generally developed from natural sources, and have not been tested in controlled studies for effectiveness or safety. Many of the products have been designated as "dietary supplements" and do not qualify as legal drugs in the United States under federal law. Instead, they are under the Dietary Supplement Health and Education Act (DSHEA) of 1994 which sharply restricts the FDA's authority in this realm of products. (Homeopathic products, which are often considered natural agents, are registered as drugs by the FDA, but are not approved by the agency.) The law now defines medicinal herbs as "dietary supplements" that are available for self-medicating without restrictions. The law doesn't prevent the FDA from acting against unsafe products, but it requires that the FDA prove lack of safety before taking action.

Regardless of the therapeutic value attached to an herb, it cannot be called a drug because it has not gone through the FDA's clinical trials to gain approval. The labels on dietary supplements may carry a statement of "nutritional support" or a structure/function statement, but it also must have a boldface disclaimer stating: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."

"IN BRIEF, SIR, STUDY WHAT YOU MOST AFFECT" — THE TAMING OF THE SHREW

While members of the health care profession may realize the potential dangers of side effects, contraindications, adverse reactions, interactions and toxicities, many consumers simply perceive herbs as a safe supplement to their diets and a boost to their already prescribed regimen. With 60 million Americans using natural products with or without the advice of a health care professional, pharmacists are forced into the role of answering consumer questions on the most up-to-date information available about the uses and effects of these products.

So, what kind of information is available on herbs and such? The latest news can be found through continuing education or correspondence classes, books, reference materials, journals, newsletters, computer programs and Internet sites. Information is so readily available through the media that many patients have educated themselves about herbals more thoroughly than the pharmacists actually selling the products.

Donna Lee, RPh and BS Pharmacy, is the president and owner of Natural Alternatives Inc. in Greensboro, which is stocked entirely with natural products. Her C.E. program "Pioneering A Natural Pharmacy Practice" presented at the Socio-Economic Seminar in March provided numerous resources she'd found worthwhile sources of information. She stressed that education using reliable sources is the key.

"Before you start putting in products, this (education) is the basis you need to start with," said Lee. She began on a small scale at her pharmacy in High Point. After an intern returned from studying in Great Britain (where natural products are much more common in the health care community), she wanted to use some of her research information to set up a display of natural products in the store as part of her project. Lee agreed and watched the small project change her entire pharmacy career.

"Response from patients was what was so intriguing," she said. "It opened up a whole new world." It opened up a whole new store in Greensboro as well in May 1996, and she also will be opening a second store later this year.

Lee has been able to forget the monotony of dispensing and to get back to working

EDUCATIONAL RESOURCES

by Donna Lee, RPh, BS Pharm
President, Natural Alternatives Inc.,
5002E High Point Road, Greensboro, NC 27407
(910) 856-1299

I. **Continuing Education Programs and Seminars**
- Bastyr University Long Distance Learning Program (206) 823-1300
- Texas Pharmacy Foundation & the American Botanical Council (800) 373-7105
- Articles in trade journals such as *Drug Topics, US Pharmacist, Pharmacy Times*

II. **Books and References**
- The Lawrence Review of Natural Products, by *Facts and Comparisons*
- The Honest Herbal and Herbs of Choice by Dr. Varro Tyler
- Natural Health, Natural Medicine and Spontaneous Healing by Dr. Andrew Weil
- Botanical Influences on Illness and Nutritional Influences on Illness by Dr. Melvyn Werbach

III. **Journals and Newsletters**
- *The Source* published by the Association of Natural Medicine Pharmacists
- *Self Healing* by Dr. Andrew Weil
- *Clinical Pearls* published by IT Services
- *Herb Research News* published by the Herb Research Foundation
- *Herbalgram* published by the American Botanical Council.

IV. **Computer Programs**
- *The Herbalist*, CD-ROM by David Hoffman
- *The Herbal Prescriber*, CD-ROM by Christopher Hobbs

V. **Internet Sites**
- Ask Dr. Weil - ***http://www.hotwired.com/drweil/***
- Healthworld Online - ***http://www.healthy.net***
- University of Pittsburgh - ***http://www.pit.edu/~cbw/altm.html***

with her patients. She is able to step in as a consultant and bridge the gap between conventional and complementary therapies, which is a necessity since many patients using herbal remedies don't inform their primary care physicians. She even gets paid for her consulting service with no complaints from her patients. Lee says her customers feel much more secure knowing that she is a licensed pharmacist, as well as a natural medicine consultant. They come to her with bags of medicines and let her use her skills as a pharmacist to help make their regimen more effective.

The key is to know what you are talking about and to work closely with other health care professionals. If you realize a patient is taking an herbal remedy that may interfere with a prescribed medicine, tell the patient, and if necessary, call the physician.

Finally, pharmacists work with drugs everyday, and patients rely on the pharmacists to warn them of any dangerous drug use. It is the pharmacist's moral and professional responsibility to be knowledgeable and to spot potential trouble. If the health care professional doesn't know that antidepressants like tricyclics or MAO inhibitors may interact with ginseng or St. John's wort, the consumer likely won't know either. Reference materials and C.E. can help, but the best advice, says Lee, is to only stock products in which you feel knowledgeable enough to distribute.

"TO BE OR NOT TO BE: THAT IS THE QUESTION." — Hamlet

Several herbal remedies have made a big splash in the market in the past few years. Ginko Biloba, which supposedly sharpens memory and concentration, topped $90 million in sales in 1997. St. John's wort sold $47.8 million to those looking to treat mild depression. And buyers spent $22.2 million in food stores, drug stores and mass merchandise hoping to prevent colds with the herb Echinacea.[1]

The numbers speak for themselves. People are buying. But what kind of research has been done to verify these supposed medicinal effects? The FDA has not lent its approval. Few pharmacy schools require students to study the use of natural medicines. So who is keeping a check on these products?

Plants and herbs have a long history with the profession of pharmacy. St. John's wort and echinacea were commonly used until late in the 19th century when chemists in Germany discovered that the natural products being used for medicines could be manufactured synthetically in more concentrated forms in a laboratory. Thus, modern-day drugs were born, and herbals began to fade to the background.

In 1938, herbal products took another hit when formal regulation of drug products was instituted under the federal Food, Drug and Cosmetic Act. Afraid that they may be stocking unapproved products, many pharmacists stopped putting herbals on the shelves altogether.

In 1993, FDA commissioner at the time, David Kessler, proposed that all herbal products be removed from the market. The public outcry brought about the DSHEA regulations of 1994, which gave herbals room to grow again by classifying them as dietary supplements and restricting the FDA's involvement.

According to DSHEA, a dietary supplement is "a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino

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Socio-Economic Seminar '98

Stormy weather and crowds arriving for NCAA Eastern Regional basketball action did not disrupt the full day of educational programs and productive discussions at the 32nd Annual Socio-Economic Seminar on March 18 in Greensboro. Over 140 participants came to the Holiday Inn Four Seasons to interact and discuss with health care professionals about the future of pharmacy.

The morning session featured three esteemed speakers who offered insight on managed care and pharmacy's role in the tumultuous world of health care. Kenneth C. Otis II, president and CEO of Blue Cross and Blue Shield of North Carolina, addressed the relationship of pharmacists to insurance companies. He outlined BCBS's plans for dealing with the rising costs of drugs and paying for cognitive services offered by pharmacists.

Otis was followed by a lively slide presentation by William K. Atkinson, president and CEO of New Hanover Regional Medical Center in Wilmington. Atkinson encouraged pharmacists to pursue change proactively and to educate decision-makers like CEOs and non-pharmacy health care students so they might understand how pharmacists benefit the whole health care system.

Chris Bodine, vice president of Health Care Services at CVS pharmacy, closed the morning session with an informed talk on trends in managed care pharmacy and where pharmacy is heading. In the long term, Bodine suggested that pharmacists should continue to offer superior customer care which will lead to eventual reductions in overall medical costs.

Continuing education opportunities on topics ranging from weight control and erectile dysfunction to natural pharmacy practices and the Asheville Project filled the afternoon session, along with a pharmacy law update by David R. Work.

Participants closed out the day with a "Town Hall" discussion on moving pharmacy into the 21st Century. Many good questions were raised and discussed, including pros and cons of an "One Voice-One Vision" organizational structure for N.C. pharmacy.

Overall, the meeting was a great exchange of ideas between those practicing pharmacy and those in leadership positions in other health care areas and NCPhA.

A Proponent's View of Herbal Medicine

by Donna Lee, RPh, BS Pharm, President of Natural Alternatives

Herbal medicine has become my specialty practice, which started in my independent pharmacy several years ago fueled by the needs and requests of my pharmacy clients. Clients have always been able to rely on their pharmacist for professional guidance in the areas of prescriptions, over-the-counter medications, self-medication and selection of products. But when I realized many were turning to health food store clerks for this information, I decided it was time to regain my turf. When I read the article in the New England Journal of Medicine that stated that 34 percent of those surveyed had sought some sort of alternative treatment and 72 percent of those did not inform any health care professional, I began to ask my clients what "other stuff" they were taking. The answers I got amazed me.

In some areas I have become known as an "expert" in this field. I feel that it is easy to be an expert when so few of my colleagues have delved into the matter. On the other hand, in 1996 and 1997, I received 81 hours of pharmacy continuing education credit hours pertaining to herbal and natural medicines that contributed to this expertise. Some of these credits came from the five-day course "Botanical Medicine in Clinical Practice" at Columbia University College of Physicians and Surgeons in New York. I turned to references such as The Lawrence Review of Natural Products published by Facts and Comparisons for the data and clinical information I use. I also use articles from the Journal of the American Medical Association, Internal Medicine, Pharmacy Times and Drug Topics for background information. So when asked about clinical studies and data supporting the use of herbal medicines, these are just a few of the resources to which I refer.

From my studies, I have developed the ability to weed through the hype and advertising. I believe this is the aspect of herbal medicine which concerns and frightens most pharmacists. Also, I believe it is our responsibility to provide sound, credible, nonbiased judgment concerning information and products. In a survey recently published by the AMA, field physicians were asked what topics they wanted more information on. Complementary and alternative medicine was listed second. Who better than a pharmacist to provide correct data pertaining to herbs? Who better than a pharmacists to provide quality, standardized products for those choosing to try a natural product? I can emphatically state that health care professionals and the public appreciate my involvement, interest and expertise. I encourage pharmacists to develop their knowledge regarding the rapidly emerging science of herbal medicine.

The Herbal Minefield

by Stephen Barrett, MD

Herbal advocates like to point out that about half of today's medicines were derived from plants. This statement is true, but misleading. Drug products contain specified amounts of active ingredients. Herbs in their natural state can vary greatly from batch to batch and often contain chemicals that cause side effects but provide no benefit.

In the United States, herbs intended for preventative or therapeutic use would be regulated as drugs under federal laws. To evade the law, these products are marketed as "foods" or "dietary supplements" without health claims on their labels. Since herbs are not regulated as drugs, no legal standards exist for their processing, harvesting or packaging. In many cases, particularly for products with expensive raw ingredients, contents and potency are not accurately disclosed on the label. Many products marked as herbs contain no useful ingredients, and some even lack the principal ingredient for which people buy them.

To make a rational decision about an herbal product, it would be necessary to know what it contains, whether it is safe, and whether it has been demonstrated to be as good or better than pharmaceutical products available for the same purpose. For most herbal products this information is incomplete or unavailable. Even worse, most published information about herbs is unreliable. Varro E. Tyler, PhD, former dean of the Purdue University School of Pharmacy and a leading authority on pharmacognosy (the science of medicines from natural sources), has observed:

"More misinformation about the safety and efficacy of herbs is reaching the public currently than at any previous time, including the turn-of-the-century heyday of patent medicines. The literature promoting herbs includes pamphlets, magazine articles and books ranging in quality from cheaply printed flyers to elaborately produced studies in fine bindings with attractive illustrations. Practically all of these writings recommend large numbers of herbs for treatment based on hearsay, folklore and tradition. The only criterion that seems to be avoided in these publications is scientific evidence. Some writings are so comprehensive and indiscriminate that they seem to recommend everything for anything. Even deadly poisonous herbs are sometimes touted as remedies, based on some outdated report or a misunderstanding of the facts. Particularly insidious is the myth that there is something almost magical about herbal drugs that prevents them, in their natural state, from harming people."

Merlin Nelson, MD, PharmD, has asked pharmacists why they promote and sell food supplements to healthy individuals who don't need them. He concluded: "The most common reason is greed. Advertising creates a demand that the pharmacist can supply and make a profit. 'If I don't sell them, they'll just go to my competition down the street,' is a common response. Pharmacists are apparently more interested in a sale than in the patient's welfare..."

I (Barrett) believe that pharmacists have as much of an ethical duty to discourage use of inappropriate products as physicians do to advise against unnecessary surgery or medical care. Very few pharmacists do so.

Stephen Barrett, MD, is a retired psychiatrist in Allentown, Penn., and the author of 44 books including "The Vitamin Pushers: How the "Health Food" Industry Is Selling America a Bill of Goods." (Excerpts are from The Herbal Minefield and Nutrition Forum Jan./Feb. 1998 "The Unethical Behavior of Pharmacists" by Stephen Barrett) For full copies of these articles, along with other information, visit www.quackwatch.com or email Barrett at sbinfo@quackwatch.com.

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acid; a dietary supplement used by man to supplement diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any ingredients described [above]." These products cannot be "use(d) as a conventional food or as a sole item of a meal or the diet."

Before DSHEA, the Food, Drug and Cosmetic Act was amended in 1962 to require that all drugs must be proven effective, not just safe, before the FDA would approve the products for distribution. The process takes an average of 12 years and with costs over $230 million to develop clinical trials to gain approval. For natural product companies that can already sell their ware, the headache is too great. Besides, most manufacturers don't have the current data available to push for FDA approval anyway.

The most extensive research on herbs is currently being done in Europe, especially Germany. The health care community there is much more accepting of natural products than in the United States. In fact, German physicians write 60 million prescriptions per year for St. John's wort.

The German Kommission E, similar to the FDA, was established in 1978 by the German Federal Health Agency to collect data on herbal products, evaluate their usefulness and safety and publish the results. The conclusions were based on manufacturers' studies, animal research, clinical studies, historical uses and experiences reported by physicians. The information was compiled in what is called an herbal monograph and are published in *Bundesazeiger*, comparable to the FDA's Federal Register. Though the Kommission was terminated in 1994, over its 16 years of existence, it published 435 monographs covering 324 herbs used in German folk medicine. It approved 200 herbs as safe and effective for self-medicating. Today in Germany, insurance companies use the monographs to determine whether an herb will be reimbursed.

The American Herbal Pharmacopeia began working on a compilation of monographs in 1997 and has completed four thus far, and the United States Pharmacopeia has worked on 11 herbal monographs. The American Botanical Council translated the German Kommission E works and are publishing them in book form this year.

In the United States, the federal government is getting involved in the scientific study of natural alternatives. Congress and the National Institute of Health (NIH) have established the Office of Alternative Medicine to look at the validity of these products. Also, the government has announced the funding of ten research centers that will evaluate alternative treatments of some chronic illnesses.

The future of herbal remedies has yet to be determined. A seven-member committed formed by DSHEA published its recommendations late last year. It recommended that the FDA establish an OTC review committee for herbal products that would approve them when scientific evidence backed up the therapeutic claims and proved safety. The deadline for instituting these changes is two years. The FDA will have to propose new regulations before the changes can be made.

(1) Figures from The Wall Street Journal, Feb. 26, 1998, "Kava: The Making of an Herbal Superstar."

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Pepsi-Cola: Born in N.C. Pharmacy

The story of Pepsi began at the turn of the century when the drugstore soda fountain was one of the most popular places for people to gather at day's end to catch up on the news and enjoy a refreshing drink. In 1898, small town pharmacist Caleb Bradham of New Bern, N.C., experimented with various mixtures of coca leaf and kola nut — thought to have extraordinary health benefits — in making a fountain drink that was delicious, aided in digestion and boosted energy. His blend of syrup, spices and soda water was affectionately dubbed "Brad's Drink" by his customers. Bradham later renamed it Pepsi-Cola, launching what soon became a national favorite.

Bradham, born in Chinquapin, N.C., attended the University of North Carolina for three years before heading to medical school at the University of Maryland. After completing his second year of medical school, his father's business failed, and Bradham was forced to move home in 1891. But two years later, a local drugstore in New Bern came up for sale, and this medical student-turned school teacher managed to purchase the store almost entirely on credit. By July 9, 1893, he was registered with the North Carolina Board of Pharmacy. However, it was his skill for mixing drinks, not drugs, that made him famous.

The soft drink industry took off when a few of the "cola" drinks concocted in pharmacies around the country became so popular that their recipes were patented and trademarked for mass distribution to other drugstores. To market his new beverage, Bradham formed the Pepsi-Cola Company in the back room of his pharmacy in 1902, selling exclusively to soda fountains. The new drink's quick popularity convinced Bradham to apply for a patent and bottle Pepsi-Cola so that people could enjoy it anywhere.

By June 1903, "Pepsi-Cola" was officially registered with the U.S. Patent Office, and business boomed. Sales leapt from 19,848 gallons in 1904 to 104,029 gallons by 1907. By the end of 1910, Bradham had established Pepsi-Cola franchises in 24 states, embodying more than 280 bottlers. This strong franchise system provided a solid foundation on which Bradham pioneered an immense corporation.

The Pepsi-Cola Company enjoyed nearly 20 years of success before experiencing a setback during the sugar crisis of World War I. The price of sugar fluctuated between high and low extremes, and the cost of doing business increased dramatically for Bradham. By 1921 only two plants remained open, and in 1923 Bradham declared bankruptcy, placing his beloved Pepsi trademark up for sale.

Ownership of the Pepsi-Cola Company changed hands several times throughout the 1920s, and the company experienced its second bankruptcy before Charles G. Guth appeared on the scene to secure the soft drink's future. A successful businessman in the height of the Great Depression, Guth aimed to reinvigorate the aching company by aiming directly for the customer. He sold 12-ounce bottles of Pepsi for a nickel each, beating his competitors' standard offering of a six-ounce drink for the same price. Touting Pepsi-Cola as "Twice as much for a nickel," Guth expanded the idea throughout the Pepsi-Cola system, resulting in great success.

Pepsi experienced an era of international growth in the 1930s as the company established franchises in Canada and registered its trademark in Latin America and the Soviet Union. Company ownership again changed hands, and new leadership employed keen strategy to prevent the sugar shortage of World War II from adversely impacting the rising company. Pepsi-Cola surged to the forefront of the national war effort, adopting a new patriotic bottle label and opening a USO Canteen in New York City where more than a million families recorded messages for their loved ones serving overseas.

Vigorous ad campaigns characterized Pepsi's phenomenal post-war growth, and by 1976, Pepsi-Cola became the single largest-selling soft drink brand in American supermarkets. At the dawn of the 1980s, Pepsi was the top brand in take home sales. The famous soft drink had traveled into outer space on a shuttle and the company crossed another new frontier in the 1980s by beginning distribution in China. By the end of the decade, more than 600 Pepsi-Cola plants were operating in 148 countries and territories throughout the world.

From New Year's Day through May of this year, Pepsi-Cola has celebrated *100 Years of Pepsi* with events across the Carolinas, including a celebration weekend in New Bern, the birthplace of the drink. The original Bradham pharmacy was restored for the event, and a statue in his honor was dedicated in the Sheraton Courtyard.

Today, Pepsi-Cola spans the globe with profits surpassing $1 billion, but Caleb Bradham's unique concoction is still the pride of the Carolinas.

R.F. Butler in front of Bradham's Drug Store, where Pepsi-Cola was invented. Butler, known as Uncle Dick, took over operating the store when Bradham determined it was time to devote his efforts to making Pepsi-Cola a success.

Bradham is pictured standing behind the counter, as he always did when mixing his special blends for the locals.

In the 1940s, models from some of the top New York agencies were featured in Pepsi-Cola ads.

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Brian Swartz, Southtowne Pharmacy, Grand Rapids, MI

"We are in a highly competitive market and Good Neighbor Pharmacy Plus gives me the support I need to survive. If you haven't looked into the GNP+ program, you owe it to yourself to check it out."
Ben Lozito, Lozito's Pharmacy, Paterson, NJ

"The Good Neighbor Pharmacy program has helped give us more of an edge in the marketplace as it assists in advertising, increased purchasing power, and increased rebates. It also helps with all the value-added programs it offers. As we grow in numbers, I see us as a force to be reckoned with and recognized by manufacturers as the best avenue in which to move their new products."
Ron Davis, Buford Road Pharmacy, Richmond, VA

"The GNP+ program has helped me return to my profit levels of a few years ago. I can economically do much more and act like a chain, but I still run my store to fit my local market."
Gary Dreyfus, Moulton Plaza Pharmacy, Laguna Hills, CA

"The advertising for Good Neighbor Pharmacy has really had an impact. Bergen Brunswig has put forth the maximum effort to help us succeed. When the Good Neighbor Pharmacy Across America promotional bus came to town, it really reinforced that we are part of a powerful group."
Tom Neale, Pharmacy Plus, Teague, TX

"Chain drug stores have been expanding rapidly in the Southeast. But Good Neighbor Pharmacy Plus cluster groups have been able to make independents competitive again. We realized we are connected and have the resources to grow our business."
Robert Sopocy, Family Drug Mart, Port St. John, FL

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GOOD NEIGHBOR PHARMACY

Botanicals in Pharmacy Practice

by David Work

Legislation passed by Congress in 1994 entitled the Dietary Supplement Health & Education Act (DSHEA) produced fundamental reform in FDA's treatment of botanical products. A key definition in this act is that of "dietary supplement" which means an herb or other botanical or a concentrate, constituent, extract or combination of any botanical that is intended for ingestion as a tablet, capsule or liquid form and is not represented for use as a conventional food or as a sole item of a meal or diet and is labeled as a dietary supplement.

Pharmacists who remember some of their pharmacy law course recall that this does not match up with the definition of a drug under the federal act or the state practice act. That familiar term is "...any article, other than food or devices, intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man...or intended to affect the structure or any function of the body of man. ..." As you can see these two definitions are different which raises the question of the propriety of pharmacists' activity in this field.

In reality, the new federal law provides that botanicals may be classified in any one of five ways. They can be new drugs, OTC drugs, traditional medicines, dietary supplements or conventional foods. It is possible, then, that such products could fall within the jurisdiction of pharmacy practice.

The North Carolina Pharmacy Practice Act, in its definition of practice of pharmacy, provides that "a pharmacist may advise and educate patients and health care providers concerning therapeutic values, content, uses and significant problems of drugs and devices; assess, record and report adverse drug and device reactions; take and record patient histories relating to drug and device therapy; monitor, record and report drug therapy. ..." While the definition does not specifically cover botanicals, it certainly could be inferred from a broad interpretation of the words "drug" and "therapy" and the reference to "patient histories relating to drug and device therapy."

Perhaps the most significant part of North Carolina law on this subject is the section on patient counseling. The pertinent part can be found at section .2504 in section (c) and (d). This reference can be viewed by anyone on the Board's website at *www.ncbop.org* under Literature. The patient counseling rule provides for obtaining patient information which includes a current list of nonprescription and prescription medications. This may take some effort on the part of pharmacists, particularly with nonprescription drugs including botanicals. Many patients consider such items as some how separate from their other drug therapy and may not remember that they consume them on a regular basis. This information is essential for the drug utilization review part of the rule which follows in section (d).

Pharmacists at continuing education meetings have regularly heard that, while the rule is referred to as the patient counseling rule, the largest amount of liability in this law lies in the drug use review part, section (d). This is the part that requires pharmacists to review on each dispensing (including refills) drug therapy for problems due to therapeutic duplication, drug-disease contraindication, drug-drug interactions (including OTC drugs), incorrect dosage or duration, drug-allergy interactions and clinical abuse or misuse. Pharmacists do not have to look too far among the botanicals to find potential problems when mixed with prescription drugs. There are claims that garlic can lower cholesterol as much as 9 percent on the average and large amounts of it can inhibit blood clotting. What kind of patient reaction would occur with a person taking high levels of garlic if an antihyperlipididemic were added to their regimen? And what about Coumadin under the same conditions? Might it also be appropriate to counsel patients on either of the above two prescription products about the use of garlic?

Some people tend to dismiss botanicals as not worthy of their consideration. It's interesting to note, however, that one of the most respected medicinal chemists at the UNC School of Pharmacy, Dr. Chet Cavilito, did his early work on garlic and his publications are in the scientific literature. For those patients on anorexiants, the concurrent use of ephedra would certainly be dangerous. And is it necessary to use both chamomile and Zantac? Many of the drugs used today came from natural sources. Digitalis, atropine, belladonna and even penicillin all have a natural background.

Some of the more prestigious pharmaceutical manufacturers have acquired companies whose primary business was in botanicals or dietary supplements. Most of these companies have a German base of operations. Such names as SmithKline Beecham, Searle, Sanofi, Rhone Poulenc Rohrer, Pfizer, Johnson & Johnson/Merck just to name a few have seen a future in these kinds of products.

There's no doubt that these products have real impact on health care and pharmacy practice. Pharmacists need to decide if they will be a spectator or participant in this expanding field.

David R. Work is Executive Director of the North Carolina Board of Pharmacy and Adjunct Professor of Pharmacy Law at the University of North Carolina at Chapel Hill.

Materia Medica

Carla Schoenberger is a 4th year PharmD candidate (May 1998) at Campbell University School of Pharmacy, Buies Creek, N.C. She has spent a month of intensive herbal training at the Association of Natural Medicine Pharmacists in San Rafael, CA, and served for two months as an assistant professor of the Herbal Medicine class at Campbell. She is interested in complementary medicine and has goals to integrate her PharmD knowledge with her knowledge of complementary medicine.

Premenstrual syndrome (PMS) affects approximately 40 percent of women. Most women report their symptoms as mild, but approximately 2-10 percent report severe symptoms. PMS has been referred to as a global term that implies a change in mood, behavior and physical symptoms in response to the menstrual cycle. The intensity of symptoms usually increase premenstrually and decrease or diminish once menstruation begins. Some of the common symptoms of PMS are: excessive water retention, acne, backache, anxiety, breast swelling and tenderness, fatigue, headaches, and mood swings. To date there is no established etiology for PMS. Some of the proposed etiologies are estrogen-progesterone imbalance, pyridoxine deficiency, prostaglandin excess, hyperprolactinemia, increased angiotensin/aldosterone activity, hypoglycemia, hormonally-induced changes in endorphin activity, abnormal magnesium metabolism and psychological dysfunction.

There are a number of dietary factors that may contribute to the severity of the PMS symptoms. These factors include: calories, fat, sugar, fiber, salt intake, food cravings and vitamins and minerals. It has been shown that women who suffer with PMS symptoms consume fewer B vitamins, half as much zinc and iron, one quarter as much magnesium and more diary products, salt, sugar, protein and fat from foods of animal origin. Women may be able to improve the symptoms of depression, anxiety, anger, fatigue and confusion by eating a high-carbohydrate, low sugar, low protein diet during the premenstrual phase.

Three of the herbal products used to treat PMS symptoms include Evening Primrose, Dong Quai and Black Cohosh.

Evening Primrose (Oenothera biennis) is a large wildflower that is native to North America. The seeds of the plant are used medicinally due to their high content of gamma-linolenic acid (GLA). GLA has been shown to relieve some of the common symptoms of PMS including depression and irritability, breast pain, fluid retention and tension headaches. Evening primrose has also been used to decrease serum cholesterol, for atopic dermatitis, to reverse neurological damage in diabetics and in rheumatoid arthritis. The mechanism of action of evening primrose is uncertain. One theory is that women suffering from PMS are depleted in prostaglandin E. GLA is a precursor to prostaglandin E, and GLA supplementation has been suggested to increase prostaglandin E. The use of pyridoxine, magnesium, zinc, niacin and ascorbic acid are compatible with evening primrose therapy because these five substances are important cofactors for the conversion of linoleic acid to prostaglandin E. At recommended doses, there has been no known side effects reported with evening primrose. The recommended dose is 1,000 mg three times a day.

Dong Quai (Angelica sinensis) is an aromatic herb that grows in China, Korea and Japan. The whole root of the plant is used medicinally. The proposed active ingredients are ligustilides and ferulic acid. This herb also contains phytoestrogens and micronutrients (iron, Vitamin A, Vitamin B12 and Vitamin E). This herb has been called the "female ginseng". Dong quai is an all purpose herb for a whole range of female gynecological problems, ranging from regulating the menstrual cycle to treating menopausal symptoms caused by hormonal changes. Dong quai also has been used for many years to treat iron deficiency, insomnia, high blood pressure and to purify the blood. The phytoestrogens or plant estrogens in the herb may relieve hot flashes, vaginal dryness and other symptoms of menopause. Scientific investigation has shown dong quai to produce a balancing effect on estrogen activity and to have a tonic effect on the uterus. Dong quai should not be used during pregnancy or if the patient typically has a heavy menstrual flow. It should not be used if the patient is on anticoagulant medication. Dong quai may cause some sensitivity to the sun and a slight laxative effect. The dosage is three times a day as follows: Dried root (or as a tea) 1 to 2 grams, tincture (1:5) 4 to 6 ml (1 to 1&1/2 tsp.), fluid extract (1:1) 0.5 to 2 ml (1/4 to 1/2 tsp.), solid extract (4:1) 125 to 500 mg.

Black Cohosh (Cimicifuga racemosa) is a perennial herb that grows in open woody areas and has been grown as far south as Georgia and as far west as Missouri. The rhizomes and roots, dried not fresh, are the parts used medicinally. Triterpenes and flavonoids are believed to be the active constituents. Black cohosh has a powerful action as a relaxant and normalizer of the female reproductive system. It may be used in cases of painful or delayed menstruation and ovarian cramps. This herb has a normalizing action on the balance of female sex hormones. Black cohosh also has been used to treat rheumatic pains, rheumatoid arthritis, osteoarthritis and in muscular and neurological pain. The exact mechanism of action of black cohosh is unknown. The herb seems to decrease the secretion of luteinizing hormone (LH). High levels of LH in the blood are often associated with hot flashes, night sweats, headaches, heart palpitations and drying and thinning of the vagina. In contrast to standard hormonal therapy with estrogens and progestins, black cohosh does not seem to affect levels of two other pitu-

itary hormones, follicle-stimulating hormone (FSH) and prolactin. In other words, the action seems to be more selective than with normal hormonal therapy. This is good because it tends to lessen side effects. Black cohosh should not be used during pregnancy. It also may cause stomach upsets. Patients taking medications to control high blood pressure should be cautioned about the use of this plant because of the potential for an additive hypotensive effect. Since no long term toxicity studies have been carried out for black cohosh, the administration should be limited to a period no longer than 6 months. For preparations and dosage, a decoction can be made by pouring water onto 1/2 to 1 tsp. of the dried root and bringing to a boil. Let it simmer for 10 to 15 minutes. This should be used three times a day. There is also a 40 to 60 percent alcoholic extract in a quantity equivalent to 40 mg of herb daily. Two to 4 milliliters of the tincture can be used three times a day. The German Commission E has found black cohosh to be effective for the treatment of PMS and dysmenorrhea, as well as nervous conditions associated with menopause.

All three of these herbal remedies have a regulatory status in the United States as a dietary supplement.

PMS impacts the lives of many women. By making lifestyle changes and using natural products, especially during the premenstrual cycle, women may be able to reduce some of the symptoms of PMS. Although these remedies have been used for many years with often impressive results, well-designed clinical studies are needed. Also a reliable reporting system for adverse effects is not yet in place. The recent establishment of the Offices of Alternative Medicine and Dietary Supplements at NIH with missions to provide research support for alternative therapies should greatly add to our present knowledge concerning the safety and efficacy of herbal therapies.

BIG CHANGES!

Dear CJP Reader,

You can anticipate some big changes in the coming issues of the Carolina Journal of Pharmacy. Beginning in the July/August issue, an eight page North Carolina Society of Health-System Pharmacists supplement will be added to the Journal format. These pages will be set aside for NCSHP news and information and will be easily recognizable by the colored pages.

This change will greatly benefit NCPhA and NCSHP members alike. Not only will it be more cost-effective for the associations, it will give you, the members, more information than ever before for free. The increased volume of information in CJP will make the Journal a great resource for pharmacists in all practice settings. More pages will mean more complete information for everyone. Each group will still provide news about the individual organizations, but now it will be available in one source for all pharmacists to stay abreast of all the ongoings in North Carolina pharmacy.

And there is more. NCPhA members can now place one-time Classified Ads free of charge. Simply call, mail or fax your ad to the Association and indicate that you are a member. It's now a free benefit that we offer to you.

Finally, NCPhA is actively seeking ways to increase membership benefits. We are asking for your help so we can better meet your needs. Please take a moment to turn to page 27 and fill out the Membership Survey. Send your responses to: Membership Survey, P.O. Box 151, Chapel Hill, NC, 27514.

Thank you for your help.
Sincerely — Your editor,
Jennifer Windley

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Homeopathy in North Carolina

William Griffin, BS Pharm, June McDermott, MS Pharm, MBA Clinical Assistant Professor, Department of Pharmacy Practice, UNC School of Pharmacy, Chapel Hill, NC, Susan Gaylord, PhD Research Associate, Program on Aging, UNC School of Medicine, Chapel Hill, NC.

Abstract

A study was conducted to examine the current status of homeopathic practice in North Carolina. Professional practitioners of homeopathy were located and asked to complete questionnaires about their backgrounds, prescribing habits, practice site demographics and their opinions regarding licensing of homeopaths. Twelve professional homeopathic practitioners with backgrounds in various disciplines were identified and eight agreed to participate in the study. Evidence suggests there may be additional unidentified professional homeopathic practitioners in this state. From this work it appears that the statewide distribution of homeopathic practitioners and homeopathic study groups is limited to western and central North Carolina.

Introduction

Alternative medicine has been gaining attention in recent years in the United States. A study by Eisenberg et al. published in the *New England Journal of Medicine* extrapolated from survey data that 34 percent of the United States population had tried some form of unconventional therapy.[1] Additionally, the researchers found that one percent of the population used homeopathy, a practice of medicine whose principles were developed in the late eighteenth century by Samuel Hahneman.[2] Because of the lack of side effects, homeopathy was seen as a welcome alternative to heroic therapies of the era such as blood letting and leeching. As a result, homeopathy occupied a significant niche in medical practice in the United States even through the later nineteenth and early twentieth centuries.[3] In 1915, there were 22 homeopathic medical schools in the United States. However, under intense pressure from the American Medical Association and with the advent of antibiotics and other medical advances, the use of homeopathy declined, and by 1930 the last homeopathic medical school was closed. Yet, homeopathy has continued to maintain a presence in American society.

Recently, there has been a resurgence of interest in homeopathy, with sales of homeopathic products climbing quite steadily in recent years. *Drug Topics* reported in 1994 that sales of homeopathic products were growing at an estimated 25 percent per year.[4] Other reports appearing in nationally circulating lay and professional press have supported this estimate for steadily increasing use.[5, 6, 7] One explanation for this growth in sales is that homeopathic products are inexpensive and are seen as safe, non-toxic alternatives to conventional therapies. Furthermore, since most homeopathic products are non-prescription drugs, they are readily available to the consumer through mail-order companies, health-food stores and pharmacies.

Besides this increasing consumer interest in homeopathy, North Carolina also enjoys a liberal Medical Practice Act, amended in 1993. The newly amended Practice Act allows licensed medical practitioners to prescribe any therapy they deem useful, including homeopathy, as long as the patient is not directly harmed by the therapy.[8] Licensed medical practitioners include medical doctors, osteopathic doctors, physician's assistants and family nurse practitioners. The new Practice Act places the burden of proof upon the Board of Medical Examiners to determine that harm has been done to the patient before the Board can revoke a practitioner's license for malpractice.

As a result of these developments, it was felt that there may be quite a few homeopathic practitioners in North Carolina guiding the therapeutic choices of patients seeking homeopathic treatment. Consequently, our goal was to identify as many professional homeopathic practitioners as possible and survey them regarding various aspects of their practices.

Methods

The participants were professional homeopaths practicing in North Carolina. For the purpose of this study, a professional homeopath was broadly defined as a practitioner who prescribed homeopathic medicines to any degree, operated out of an established office, kept patient records and received payment for homeopathic care given. ("Lay" homeopathic practitioners would include anyone not meeting our working definition of a professional homeopath.) Potential participants were first located by using the National Center for Homeopathy's published list of homeopathic practitioners in North Carolina.[9] As practitioners were contacted either by telephone or personal visit by the study coordinator, they were screened for eligibility and asked to identify other homeopathic practitioners in order to locate more participants. Additionally, the moderators of homeopathic study groups around North Carolina were also solicited to help locate professional practitioners. The potential participants were then mailed a letter explaining the study, the questionnaires and a consent form. Afterwards, follow-up telephone calls were made to help bolster participation and answer any questions about the study.

Eligibility for inclusion in the study was determined during the initial contact with the practitioner by asking simple questions that related to the operating definition of being a professional homeopath. More detailed information was gathered using written questionnaires designed to be completed by the participants. The questionnaires requested information about the practitioner's background, practice site demographics, prescribing habits and opinions regarding licensure. The questionnaires were reviewed by the University of North Carolina Committee on the Protections of Rights of Human Subjects prior to being used. Data was collected from September 1 to December 31, 1995. Each participant in the study was required to read and sign a consent form before participating.

Results

By talking with five known homeopathic practitioners and six active homeopathic study groups, 17 homeopathic

practitioners were located. Of these 17, 12 met the requirements for inclusion in the study. This group of 12 practitioners received training in a variety of health care disciplines before they began using homeopathy in their practices. Eight of these practitioners returned completed questionnaires. One naturopath, one chiropractor and two medical doctors elected not to participate due to time constraints or reservations about confidentiality. Primarily, the practitioners were located in the central and western regions of North Carolina, with only one practitioner operating in the eastern region of the state.

Of the eight practitioners responding to the survey, only one indicated the exclusive use of homeopathic methodologies. The other seven practitioners would, if necessary, use other modalities particular to their original training. Considering the seven practitioners, one indicated the use of homeopathic medicines less than 25 percent of the time, while the others indicated usage rates greater than 50 percent.

The eight respondents provided information on their practice site demographics. All the practitioners reported growth in their practices and as a group, they estimated that they saw an average of 245 new patients during the first nine months of 1995. Also as a group, they averaged 12.6 daily patient visits per office site at the time of the study. Additionally, every practitioner reported having an office staff that consisted of at least one receptionist. However, the practitioners usually reported having a receptionist as well as working with other types of health care providers so the average number of office workers was 3.8.

Conclusion

Professional homeopathic practice in North Carolina may appear limited in number, but the legal environment coupled with the public's interest indicates there is much potential for growth. It is thought that there are more professional homeopathic practitioners working in North Carolina than found for this study. And certainly, if the scope of the study were expanded to include lay practitioners, the numbers would greatly increase. Conventional health care practitioners need to be aware of the presence of homeopathy as well as other alternative medical practices in their area and that their patients may be using these modalities. This will reduce the potential for problems with conflicting health care advice.

** A complete copy of this research study can be obtained by contacting June McDermott, UNC School of Pharmacy. Information includes copies of questionnaires used, research discussion and multiple graphs and figures.

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A Son's Story

I am celebrating my first birthday this week, probably the best one I've ever had. Actually, it's been one year of recovering from drug addiction, filled with pain and happiness, ranging from the loss and subsequent reinstatement of my pharmacy license to the most wonderful personal growth I've ever experienced in my life.

Like many recovering pharmacists and other professionals, I began my drug use through experimentation in college. I drank in high school occasionally, always being the one who "drank too much." In college, I experimented with various drugs while living in the dorms, until I tried cocaine. Then, for the first time in my life, I found a substance which made me feel no bad emotions, or so I thought. For the most part, cocaine became my drug of choice.

The problem was that I had always set myself up to be the best in everything that I did. The pressure began to get to me in college, and I enjoyed the relief that drugs gave me. The truth of the matter was that I had never learned to live life on life's terms. I was always having to run or escape.

While many of my college friends knew when to stop using alcohol or other drugs, I did not. I never wanted the "fun" to stop. In all actuality, I just wanted to stop feeling. Since money in college was limited, I was often able to "make" myself stop. I also felt it was important to get my pharmacy degree. Somehow, some way, I was able to graduate. But for the next 10 years of my life, I endured a battle with an inner self that I felt I didn't know and couldn't control. Whatever I did that seemed to alleviate the pain of feeling emotions, I did, and did it to extremes. I made a pact with myself to stop using cocaine; it was "too dangerous and too addictive." I often threw myself into work, agreeing to take all the overtime I could, doing the best that I could. Surely money or the distinction of being "super-pharmacist" would help heal this unexplained pain. When I finally became physically burnt out, I decided to use an old stand-by to help me again — Cocaine. This time, though, was different. I had money and could isolate myself from friends and family. I began to throw myself into using cocaine again. Unlike the "successful" using in the past, I couldn't fight this inner drive anymore. The astounding fact was that I still thought I had control, even as my life was disintegrating.

After one unsuccessful attempt to seek help on my own, I was finally caught, (though now I choose to use the word rescued), by the Board of Pharmacy. The day I surrendered myself to getting help was the day I finally began to live. As a patient at a 3-month treatment program designed for impaired professionals, I learned how to feel emotions, and also how to deal with them. I learned I no longer had to use drugs, as long as I followed the program. My family, showing love in spite of all the pain I caused, began to educate themselves about the disease of addiction and how to support my recovery. Most important for me is my attendance at 12-step support groups like Narcotics Anonymous.

Upon my release from the treatment center, NCPRN began not only the monitoring of my abstinence from drugs, but also helping me plan for a life without mood altering chemicals. I am so grateful to NCPRN, and to Dave Marley, the executive director, for offering this life saving program. NCPRN will help me to celebrate many more "birthdays" to come.

His Mother's Lament

The truth came out one cold, November night two years ago. My husband, a pharmacist, and I were called upon once again to come to our oldest son's aid. We were frustrated because our otherwise responsible son, who is also a pharmacist, had recently been in a constant state of turmoil. Upon our arrival, we inquired once again as to his inability to handle the daily stresses of his life. He finally admitted that he was unable to cope without the use of drugs.

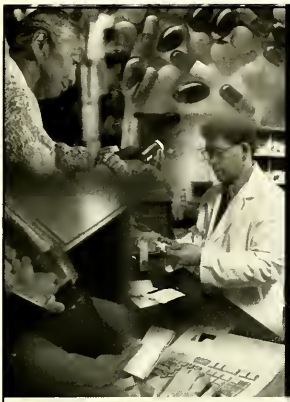
Our son was our pride and joy, always producing top grades, winning honors for his leadership, being active in his church, yet he was never happy with himself. He could not blame his problems on a dysfunctional family, nor could he pinpoint his reasons except that once he tried a chemical substance, he could not stop. At age 31, our son lost everything — his home, his car, his pharmacy license, his self respect and very nearly his life.

Today our son is working on his healing and getting his life back together. I believe this was only possible through the grace of God, and His leading us to Dave Marley and NCPRN. Dave has been a trusted friend and advocate for pharmacists and pharmacy students dealing with the same problems that our family experienced. His advice led my son, and us, to the Farley Center in Virginia, where we have all learned to live with our son's disease.

Personally, I have had to view issues that I had been self-righteous and judgmental about before. Alcohol and substance abuse were issues for others to deal with — our family could not be touched by degrading things such as these. But it was, and we would not give in to defeat to such strongholds, nor would we shut the door on our hurting loved one. Fortunately, we didn't have to look very far for the help we needed.

The profession of pharmacy has much to take pride in because of the acknowledgment of the problems that exist in today's society. By creating NCPRN, these highly trained professionals can again become productive and live drug-free through education and advocacy. My hope is that other agencies and professional groups would look to the NCPRN program as an effective example of dealing with these issues that are taking the lives of the youth of our country.

Allow me to express my appreciation to Dave Marley, NCPRN, Jack Watts (president of the Board of Pharmacy), members of the Board of Pharmacy, and finally, to the NC House of Representatives for acknowledging and establishing House Bill #948 for the rehabilitation and recovery for pharmacists.



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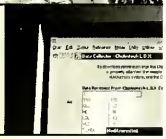

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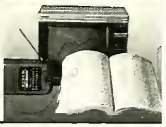

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University of North Carolina - Chapel Hill

by Kevin Almond, B.S. Pharm, Assistant Dean

The spring semester at UNC has been busy with activity outside the classroom, giving students numerous opportunities to learn about the profession. In mid-March, Barbara Zarowitz, PharmD, of the Henry Ford System in Detroit, became the eighth Howard Q. Ferguson Memorial Lecturer, spending two days in various classrooms talking with our students. Her open lecture, "Integrated Health Systems: Challenges and Opportunities for Pharmacy," was held at the George Watts Hill Alumni Center. Later in March, 34 students traveled to Miami for the annual meeting of APhA and its student academy. Students sat in on meetings, attended the House of Delegates, and returned with bags of promotional material from their walk through the exhibit hall.

In early April, Ray Marcrom of Manchester, Tenn., came to Chapel Hill as the practitioner-in-residence. Ray spent two days talking to groups of students about his innovative practice and the opportunities that abound in community pharmacy and ambulatory care. His innovative practice had many students thinking about future pharmacy ownership. The rest of April brought a severe case of spring fever to students and faculty alike, as the UNC campus sprung forth with blooming azaleas, dogwoods and redbuds, and everyone began looking past final exams to the end of the school year.

Campbell University

by Thomas J. Holmes Jr., PhD
Associate Dean for Student Affairs

The 1997-98 school year provided many new opportunities for expansion and enhancement of our programs. Two new student organizations were founded: a student committee of the North Carolina Society of Consultant Pharmacists and a student chapter of the Academy of Managed Care Pharmacy. Our local chapter of the Student National Pharmacists Association was reinvigorated by new leadership and aggressive programming. A significant lobbying effort on behalf of the amended North Carolina Pharmacy Practice Act has been initiated by students and faculty with hopeful promise for the future.

Campbell pharmacy students have been recognized for national and regional achievement during the year: senior Dena Askew was awarded a Parke-Davis/Warner Lambert Commitment to Excellence Award in the fall, and senior Darrell Haymore was recognized this spring for submitting the best manuscript on Stage III and IV Congestive Heart failure in the U.S. Pharmacist/Sanofi Corporation Essay Challenge contest. Rising senior Angela Turner has been awarded a North Carolina Schweitzer Fellowship for a project to be completed this summer, and she led the way as president along with fellow officers Amanda Corbett and Ed Millikan in capturing 3rd place in the national Phi Lambda Sigma Leadership Challenge competition.

This year Parents' Day was held on April 4th and students receiving various honors and scholarships throughout the academic year were recognized for their outstanding achievements.

Graduation ceremonies for the Class of 1998 were on May 10th with the hooding of our 89 Doctor of Pharmacy graduates. The event featured guest speaker William Arthur Shore, director of the corporate and community affairs at GlaxoWelcome Inc. Commencement ceremonies took place on May 11th.

Campbell University School of Pharmacy recognizes a North Carolina pharmacist annually for his/her contribution to the practice of retail pharmacy with M. Keith Fearing Retail Pharmacy Award. This year the award was presented at graduation to James L. Creech, RPh.

On the faculty side, Associate Professor, Peggy Yarborough, has recently been awarded a grant from the Kate B. Reynolds Charitable Trust to expand her Diabetic Outcomes Management program to the Wilson area. The following new faculty members have joined us this year: Tim Bloom, PhD, Assistant Professor of Pharmaceutical Sciences in Buies Creek; Richard Drew at the Duke University Medical Center in Durham; Michelle Fritsch, PharmD, at Alamance Regional Medical Center in Burlington; Kathy Fulton, PharmD, at Pitt Regional Medical Center in Greenville; and Vanessa King, PharmD, at Cape Fear Valley Medical Center in Fayetteville.

Now it is May and many of our students are leaving for residencies, graduate programs and practice sites. This May we have 46 BS Pharmacy graduates and 71 PharmD graduates, most of whom are ending their days here in Chapel Hill. Garland Hershey, former vice chancellor of Health Affairs and UNC School of Dentistry professor, will give the commencement address. Dean Campbell and the rest of the faculty and staff wish the class of 1998 the best as they move down their various career paths.

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Pharmacists in the news...

• **Ronald H. Small** was presented the Academy of Pharmacy Practice and Management Distinguished Achievement in Hospital and Institutional Practice Award sponsored by Wyeth-Ayerst Global Pharmaceuticals, at the 1998 APhA Annual Meeting in Miami Beach, Fla., in March. He was selected in recognition of his commitment to the pursuit, development and continuity of pharmaceutical care at North Carolina Baptist Hospitals. He is the director of pharmacy at Wake Forest Baptist Medical Center in Winston-Salem. He earned his BS and MBA from the University of North Carolina. He is an adjunct professor of pharmacy practice with the UNC and Campbell Schools of Pharmacy and a lecturer in hospital administration at Wake Forest University. He has contributed to the professional body of knowledge on such topics as TQM, pharmacoeconomics and pharmaceutical care, including the concept of continuity of care.

• **Dennis M. Williams**, PharmD, was presented with APhA's Academy of Pharmacy Practice and Management Distinguished Achievement Award in Clinical/Pharmacotherapeutic Practice. Williams is an assistant professor in the School of Pharmacy at UNC and a clinical specialist in pulmonary medicine at UNC Hospitals. He also maintains a clinical practice in pulmonary medicine and infectious diseases, where he is involved with patient care in both in-patient and ambulatory services, and contributes greatly to the body of clinical knowledge in these areas. He received his BS and PharmD degrees from the University of Kentucky, and he is a board-certified pharmacotherapy specialist. Williams' primary focus in practice, teaching and research are pulmonary diseases, including asthma, COPD and cystic fibrosis, and infectious diseases, including HIV infection and AIDS.

• **Larry Seigler**, vice president of human resources and corporate affairs at Catalytica Pharmaceuticals Inc. in Greenville, N.C., was named Citizen of the Year by the Greenville-Pitt County Chamber of Commerce. He played a large role in the transitioning of the county's largest industrial site from Glaxo Wellcome to Catalytica Inc. He earned a BS in pharmacy from UNC 1970 and worked for a short while at Duke Medical Center in Durham before moving to Pitt County in 1971. He has worked at his present position for 26 years, through the Burroughs Wellcome/Glaxo merger, and the most recent change in ownership. Seigler's current community activities include leadership in the Pitt County Educational Foundation, Communities in School of Pitt County, United Way of Pitt County, Pitt County Substance Abuse Council, Smart Start Program and Pitt County Art Council.

• **Carl Dewey Taylor**, a 1968 UNC School of Pharmacy graduate, was recognized in an article in the March/April Issue of the Carolina Alumni Review for his revitalization of the Roanoke-Chowan alumni club and other commitments to the University. He helps counsel students in Gates County considering college, and has personally endowed a Carolina scholarship. He also takes on pharmacy school students as interns and has worked on developing the external pharmacy doctorate program for practicing pharmacists.

• **Dr. Andrew D. McBride** of Connecticut has accepted the invitation to join Secretary H. David Bruton of the Department of Health and Human Services as Assistant Secretary, effective May 4. McBride attended high school in High Point before earning his medical degree from University of Pennsylvania and his public health degree from Yale. He is also a pediatrician, who received his training at Children's Hospital in Philadelphia.

• The official construction of the new facilities for **ATP Inc.**, Partners in Health Information Services, began March 13. The future 24,750 square foot building will be located in Meridian Park in the Research Triangle. President and CEO **Mary Lynn Bell**, RPh, is thrilled with the growth ATP (formerly Ask the Pharmacist) has experienced over the last seven years. The office is currently utilizing 14,000 square feet in the Europa Center in Chapel Hill.

• **Mr. Leonard R. Creech** Sr., 86, of Oxford, died February 17 in Brantwood Nursing and Retirement Center. Creech, a 1933 UNC School of Pharmacy graduate, was a retired pharmacists with Williams Drug Store.

IN THE NEXT ISSUE:

Look for news on the Asheville Project and reports from the 1998 NCPhA Convention

Patient Counseling: New Anti-HIV Drugs of 1997; Part 2: Anti-HIV Drugs

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Goals. The goals of this two-part lesson are to discuss new anti-HIV drugs and current concepts in the therapy of AIDS as published in reports by the National Institute of Health and the Department of Health and Human Services in 1997; and review the benefits of combination therapy with anti-HIV drugs, their mechanisms of action and the importance of compliance with therapeutic regimens.

Objectives. At the conclusion of this lesson, the participant should be able to:

1. select correct information about current concepts in the treatment of HIV infections;
2. choose appropriate information about the pharmacology of anti-HIV drugs; and,
3. demonstrate an understanding of important information to convey to patients receiving anti-HIV drugs.

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Two new drugs for treating HIV infections were approved by FDA in 1997: nelfinavir [Nel-fin-a-veer] (Viracept) [Veer-a-sept], a protease inhibitor and delavirdine [dela-veer-dean] (Rescriptor) [Ree-skript-oar], a non-nucleoside reverse transcriptase inhibitor.

The first combination anti-HIV drug (Combivir) was introduced to the market in 1997. Combivir contains zidovudine (Retrovir) with lamivudine (Epivir). It is recommended for twice a day dosage, which reduces the number of tablets per dose, eliminating a previously more complicated regimen.

Human Immunodeficiency Viruses and Anti-HIV Activity

There are three groups of anti-HIV drugs currently on the market: nucleoside reverse transcriptase inhibitors; non-nucleoside reverse transcriptase inhibitors; and protease inhibitors. The currently available drugs in each class are listed in Table 1.

Viruses are not "living" organisms. They cannot move, metabolize needed substances, grow or reproduce. They consist of a core of RNA or DNA surrounded by a protein shell. Some viruses have a lipid/glycoprotein envelop called a capsid.

Pathogenic viruses have the ability to connect chemically with the surface of susceptible living cells (host receptor sites). With HIV, the initial human host cells are the T-helper cells which are extremely important to our immune system. After connecting with the host's cells, pathogenic viruses enter and invade their nucleus. Pathogenic viruses contain the enzymes they need to replicate within their envelop. For HIV, the major enzymes are reverse transcriptase, protease and integrase.

After conversion of the virus into its pathogenic form, its core DNA/RNA strand enters the nucleus of the host cell, incorporates itself into the host's genome, and in essence takes over the genetic coding of that cell to replicate itself. Eventually, the host cell is destroyed and viral progeny escape to attack other susceptible cells. With HIV, when sufficient T-helper cells are destroyed, the patient is immunodeficient.

Basically, the anti-HIV drugs are "antimetabolites" in that they interfere with HIV enzymes and prevent viral protein and DNA/RNA synthesis.

Nucleoside Reverse Transcriptase Inhibitor Action

These drugs are nitrogen-containing chemicals that closely resemble one of the building blocks of DNA/RNA. They inhibit elongation of the viral DNA chain before it is inserted into the human host cell's genome. While they delay progression of Acquired Immunodeficiency Syndrome (AIDS) symptoms, reverse transcriptase inhibitors have no effect on cells in which the viral genome has already been incorporated into the host's genome. Unfortunately, resistance develops and they can produce significant adverse effects such as bone marrow depression and neuropathies.

Non-Nucleoside Reverse Transcriptase Inhibitor Action

These agents inhibit the activity of reverse transcriptase in a manner independent of nucleoside linkage. This means that while the nucleoside reverse transcriptase inhibitors compete with the linking of HIV DNA components to polymerize them into their progeny, these drugs bind directly to reverse transcriptase and disrupt its catalytic activity. They are synergistic to the nucleoside reverse transcriptase inhibitors.

Protease Inhibitor Action

The protease inhibitors suppress viral replication after DNA has been incorporated into the human genome. Protease cleaves viral precursor polypeptides into infective virions. Therefore,

Table 1
Anti-HIV Drugs Currently on the Market

Generic Name	Trade Name	Availability
1. Nucleoside Reverse Transcriptase Inhibitors		
Didanosine	Videx	tablet, powder (capsule soon)
Lamivudine	Epivir	tablet, oral solution
Stavudine	Zerit	capsule, powder for oral solution
Zalcitabine	Hivid	tablet
Zidovudine	Retrovir	capsule, tablet, syrup, injection
Lamivudine plus Zidovudine	Combivir	tablet
2. Non-Nucleoside Reverse Transcriptase Inhibitors		
Delavirdine	Rescriptor	tablet
Nevirapine	Viramune	tablet
3. Protease Inhibitors		
Indinavir	Crixivan	capsule
Nelfinavir	Viracept	tablet, powder
Ritonavir	Norvir	capsule, oral solution
Saquinavir	Invirase	capsule
	Fortovase	gelatin capsule (more bioavailable)

these drugs prevent viruses from becoming pathogenic rather than preventing them from reproducing.

Protease inhibitors are active even in cells that are not replicating. They are synergistic to the reverse transcriptase inhibitors and represent a major advance in the treatment of HIV infection.

Combination Therapy

While the currently available anti-HIV drugs do not eradicate the infection, combination therapy (in the proper dosage and with full compliance) can decrease viral replication, improve the patient's immunologic capability, delay the onset of complications from infections by opportunistic organisms and prolong life. However, undertreatment by physicians and lack of compliance by patients has lessened the success of these drugs in some patients. Proper therapy entails 30 to 50 doses of drugs at unusual intervals during the day, sometimes with food and sometimes on an empty stomach.

Nucleoside Reverse Transcriptase Inhibitors

Didanosine (Videx) is available in 25, 50, 100 and 150mg chewable/dispersible tablets, packets containing powder for solution with 100, 167, 250 and 375mg of didanosine, and bottles of powder for suspension containing 2 and 4 grams of didanosine. A capsule dosage form may soon be available commercially.

The dosage for Videx is 200mg twice a day for patients weighing more than 60kg, and 125mg twice a day for patients weighing less than 60kg. The drug is degraded by gastric juices so it should be taken on an empty stomach.

Two tablets are required for each dose in order to provide adequate buffering to protect didanosine from gastric breakdown. They must be chewed thoroughly, and ground up or dissolved to disperse the drug properly and maximize absorption. The tablets are difficult to chew. They can be dissolved in one ounce of tap water to make it easier, but the manufacturer states that it is best not to use other liquids because of potential pH problems.

Videx is also available as packets of powder for solution and bottles of powder for suspension. The directions for preparing the powder for solution is to add the contents of a packet to four ounces of water, stir for several minutes to assure dissolution and then drink the liquid right away.

The initial dilution of the powder for suspension is made with 100ml of purified water for the two gram bottle and 200ml of purified water for the four gram bottle to provide 20mg/ml. This must be mixed immediately with an equal portion of double strength aluminum/magnesium antacid (e.g., Mylanta Double Strength or Maalox Therapeutic) to provide a properly buffered 10mg/ml suspension. The suspension should be dispensed in a regular prescription bottle. The suspension should be shaken well before each dose, refrigerated between doses, and discarded 30 days after the date of preparation.

The manufacturer warns that patients on Videx should not take acetaminophen without their physician's knowledge due to the potential for drug interaction.

Didanosine is used mainly in combination with zidovudine or stavudine, but not zalcitabine due to similar toxicities. It is also reported to impair absorption of indinavir when taken concurrently. Doses should be separated by at least one hour.

Significant adverse effects with Videx include pancreatitis (for which there is a boxed warning), peripheral neuropathy, nausea and diarrhea. Patient monitoring involves performing periodic serum amylase level and liver function testing.

Lamivudine (Epivir) is available as 150mg tablets and a 10mg/ml oral solution. The dosage for Epivir is 150mg twice daily in combination with zidovudine. The combination product (Combivir) facilitates compliance. The manufacturer provides a chart including lower dosages for patients with impaired renal function based on the results of creatinine clearance testing. Food does not affect absorption appreciably, so the dose can be taken with or without food.

When Epivir was approved, there were insufficient data to determine significant adverse effects. Since it is used in combination with zidovudine, the adverse effect profile for that drug should be considered. Compliance is critical as with all anti-HIV drugs.

Patient monitoring for lamivudine would also include serum amylase levels and liver function testing.

Stavudine (Zerit) is available in 15, 20, 30 and 40mg capsules.
The dose is 40mg every 12 hours for patients weighing over 60kg,
and 30mg every 12 hours for persons under 60kg. Its absorption does not

appear to be affected by food.

Zerit is reported to be used most often as a substitute for zidovudine in initial combination therapy, or after failure of zidovudine-containing regimens. It is also reported to be synergistic with didanosine and lamivudine, but may be antagonistic to zidovudine.

As with Epivir, when Zerit was approved, there were insufficient data to determine significant adverse effects, with the exception of peripheral neuropathy for which there is a boxed warning. Patients should be advised to watch for signs of peripheral neuropathy which include tingling, burning, pain or numbness in the hands or feet.

Patient monitoring during therapy with Zerit involves signs of peripheral neuropathy, full blood counts, liver function and serum amylase level testing.

Zalcitabine (Hivid) is available as 0.375 and 0.75mg tablets. The usual adult dose is 0.75mg every eight hours. Absorption is decreased when Hivid is taken with food, but apparently not enough to recommend administration on an empty stomach.

Adverse effects of note are peripheral neuropathy and pancreatitis (for which there is a boxed warning) and stomatitis (inflammation of the mouth). Patient monitoring should include signs of peripheral neuropathy and serum amylase levels.

Zidovudine (Retrovir) is available in 100mg capsules, 300mg tablets, 10mg/ml syrup and 10mg/ml injectable dosage forms. The usual adult dose is 300mg twice a day or 200mg three times a day, depending on what other drug is used in combination therapy. Absorption is reportedly not affected by food.

Adverse effects of note are bone marrow suppression (for which there is a boxed warning), gastrointestinal upset, headache and insomnia. Patient monitoring involves full blood counts and liver function testing. Creatinine phosphokinase (CPK) levels should be monitored if symptoms of myopathy occur during the first year of therapy. Some experts recommend that CPK level testing be performed every two months after the first year of therapy.

Non-nucleoside Reverse Transcriptase Inhibitors

Delavirdine (Rescriptor) is available in a 100mg tablet dosage form. The dose is 400mg three times a day with food or on an empty stomach. For patients unable to swallow the tablets, they can be dispersed in at least three ounces of water and then swallowed right away. The dose should not be taken within one hour of an antacid as this will decrease absorption.

Adverse effects of note are rash (quite prevalent), nausea, vomiting and headache. Patients need to be monitored for severe rash or rash accompanied by fever, blistering, oral lesions, conjunctivitis, swelling, or muscle or joint aches. If these occur, the patient should stop taking the drug and call the physician immediately.

Nevirapine (Viramune) is available in a 200mg tablet dosage form. Its dosage regimen is 200mg once a day for 14 days, then 200mg twice a day. The dose can be taken with or without food. The lower initial dose, which is increased after 14 days, reportedly lessens the incidence of rash which can be severe to life-threatening. Hepatitis is the other adverse effect of note.

Patient monitoring involves observation for severe rash or rash accompanied by fever, blistering, oral lesions, conjunctivitis, swelling or pain in muscles or joints. If these occur, the patient should stop taking the drug and call the physician immediately. Serum transaminase levels and liver function tests are also important.

Protease Inhibitor Drugs

Indinavir (Crixivan) is available as 200 and 400mg capsules. The usual adult dose is 800mg every eight hours with water on an empty stomach, one hour before or two hours after a meal. The dose can be taken with other fluids such as skim milk, juice, coffee, or tea, or with a light, low-fat snack such as dry toast with jelly or corn flakes. The manufacturer makes special mention that the capsules are sensitive to moisture and should be stored in their original, tightly sealed container, with the desiccant intact.

The manufacturer recommends that when indinavir and didanosine are administered concomitantly, they should be taken at least one hour apart on an empty stomach because of the buffering agent in didanosine.

Adverse effects of note are kidney stones, gastrointestinal upset and nausea. Because of the potential for kidney stone development, patients should be advised to drink at least 1.5 liters (48 ounces) of fluids daily. Patient monitoring involves liver function testing and watching for signs of kidney stone formation (flank pain and blood in the urine).

The effectiveness of protease inhibitors was so remarkable during initial testing that they have been approved for marketing by FDA in a matter of weeks rather than months. Proper dosage regimens and strict compliance are necessary to achieve these results.

Nelfinavir (Viracept) is available as a 250mg tablet and 50mg/g powder. The usual adult dose is 750mg three times a day with a meal or snack. The powder form is used for pediatric patients or adults who cannot swallow the tablets. The dose (one scoop equals 50mg) can be mixed with a small amount of water, milk or dietary supplement, and taken within six hours of mixing. It should not be taken with acidic foods or juices because they will not mask the bitter taste of the drug.

Although Viracept inhibits the CP450 enzyme system, it is also metabolized by the same system. The manufacturer states that its action can be increased or decreased by other anti-HIV drugs, and this should be taken into consideration when prescribing Viracept.

Adverse effects of note are diarrhea (which reportedly can usually be controlled by OTC loperamide), hematologic abnormalities, nausea and flatulence. Patient monitoring involves full blood count testing.

Ritonavir (Norvir) is available in 100mg capsules and an 80mg/ml oral solution. The recommended dose is 600mg twice a day with food. Some patients experience significant nausea at this dose, and may better tolerate Norvir if the dosing is begun at 300mg

twice a day and titrated upward to 600mg over several days.

The capsules should be stored in the refrigerator, and the solution refrigerated until dispensed. It is recommended that the solution be refrigerated after dispensing, but it may be stored at room temperature if it will be used within 30 days. The taste of the solution may be improved by mixing it with chocolate milk or a liquid dietary supplement within one hour of taking it.

Adverse effects of note are nausea, vomiting and diarrhea, numbness/tingling of the mouth and/or extremities, hepatitis and elevated triglyceride levels. Patient monitoring involves liver function tests, and triglycerides, transaminase, CPK and uric acid levels.

Saquinavir (Invirase/Fortovase) is currently available as 200mg capsules (Invirase). A 200mg soft gelatin capsule dosage form (Fortovase) with greater bioavailability was approved in late 1997 and will replace the original Invirase capsules in 1998. Fortovase contains saquinavir in an oil-like substance that allows microdispersion upon contact with gastric fluids. More saquinavir is absorbed from the intestines because digestive enzymes are less able to degrade it. The average amount absorbed from the newer, soft gelatin capsule is over three times greater (331 percent) as compared to the original hard gelatin capsule. Fortovase capsules should be refrigerated. If, for some reason they are brought to room temperature, they should be used within three months. The recommended dose for Invirase is 600mg three times a day within two hours after a full meal.

Adverse effects of note for saquinavir are diarrhea, nausea, gastrointestinal upset, flatulence, photosensitivity and insomnia. Patient monitoring involves liver function tests.

Since the protease inhibitors were initially approved and marketed, a general warning has been added to their labeling advising that "new onset diabetes mellitus, exacerbation of pre-existing diabetes mellitus and hyperglycemia have been reported during post-marketing surveillance." This applies to all protease inhibitors.

Conclusion

The anti-HIV drugs do not cure HIV infections, but properly dosed can decrease viral replication, improve the patient's immunologic capability, delay the onset of complications from infections by opportunistic organisms, prolong life and provide encouragement to otherwise hopeless patients that someday soon a cure will be discovered.

At present, experience shows that combination therapy with at least three anti-HIV drugs in the proper dosage and with strict patient compliance is the best method to maximize effective therapy.

IMPORTANT: WE WANT YOUR INPUT!

Please take a moment to fill out the following Membership Survey and return it with your completed C.E. quiz (or return a copy separately if you prefer confidentiality.) We are asking these questions so we can better serve our membership. Your thoughts and comments are important to us and will be considered.

1. What benefits do you feel you receive as a member of NCPhA?

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2. What benefits would you like to see obtained for NCPhA members?

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3. What do you perceive as the biggest problem facing pharmacy today?_____

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4. What can NCPhA do to help alleviate these problems? _____

_____

_____

_____

5. Should pharmacy establish an "One Voice-One Vision" organizational structure? YES NO

6. What can NCPhA do to attract new members? _____

_____

_____

7. Have you encouraged a pharmacist to join NCPhA in the past year?
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8. Are you active in a local/regional/other Pharmacy Association?
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In which county do you practice pharmacy/live? _____

Feel free to make more comments on a separate sheet of paper.
* Send to: NCPhA, P.O. Box 151, Chapel Hill, NC 27514-0151.
Thank you for your help in making NCPhA a better organization.
If you have any membership questions, please call 1-800-852-7343.

Continuing Education Quiz

Patient Counseling: New Anti-HIV Drugs of 1997; Part 2: Anti-HIV Drugs

1. The class of anti-HIV drugs that inhibits elongation of the viral DNA chain before it is inserted into the human host cell's genome is the:
   a. integrase inhibitors.
   b. nucleoside reverse transcriptase inhibitors.
   c. protease inhibitors.
   d. non-nucleoside reverse transcriptase inhibitors.

2. Combivir contains:
   a. lamivudine and zidovudine.
   b. didanosine and lamivudine.
   c. zalcitabine and zidovudine.
   d. stavudine and didanosine.

3. Nelfinavir is classed as a(an):
   a. integrase inhibitor.
   b. nucleoside reverse transcriptase inhibitor.
   c. protease inhibitor.
   d.non-nucleoside reverse transcriptase in hibitor.

4. The trade name for the drug referred to in question 3. above is:
   a. Invirase. c. Rescriptor.
   b. Viracept. d. Viramune.

5. Patients taking which of the following should be told to take each dose on an empty stomach?
   a. Epivir c. Retrovir
   b. Zerit d. Crixivan

6. The class of anti-HIV drugs that suppresses viral replication after DNA has been incorporated into the human host cell's genome and prevents viruses from becoming pathogenic is the:
   a. integrase inhibitors.
   b. nucleoside reverse transcriptase inhibitors.
   c. protease inhibitors.
   d. non-nucleoside reverse transcriptase inhibitors.

7. All of the following statements about Videx are correct EXCEPT:
   a. patients should be counseled that it is okay to self-medicate with acetaminophen but not aspirin.
   b. after it is initially dissolved, the powder for suspension dosage form must be diluted with an equal amount of a double strength aluminum/magnesium antacid before dispensing.
   c. patients taking the tablets should be counseled to take two tablets for every dose to assure proper buffering of the drug.
   d. the powder for solution dosage form should be added to four ounces of water and the resulting solution should be ingested right away.

8. Delavirdine is classed as a(an):
   a. integrase inhibitor.
   b. nucleoside reverse transcriptase inhibitor.
   c. protease inhibitor.
   d. non-nucleoside reverse transcriptase inhibitor.

9. The trade name for the drug referred to in question 8. above is:
   a. Invirase. c. Rescriptor.
   b. Viracept. d. Viramune.

10. The general warning that has been added to the labeling of protease inhibitors refers to the potential of developing which of the following diseases?
   a. Essential hypertension
   b. Bronchial asthma
   c. Congestive heart failure
   d. Diabetes mellitus

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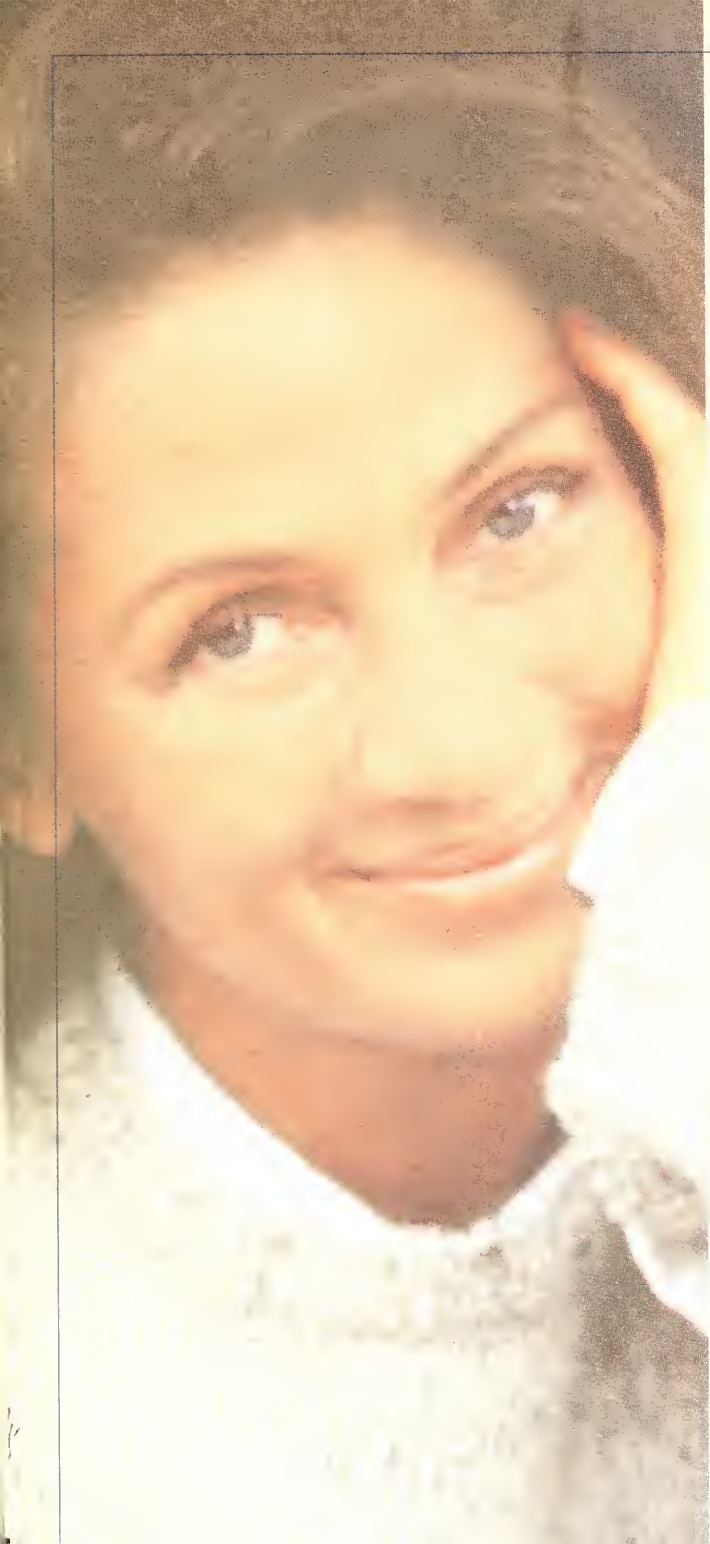

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CONTRAINDICATIONS SYNTHROID is contraindicated in patients with untreated thyrotoxicosis of any etiology or an apparent hypersensitivity to thyroid hormones or any of the inactive product constituents. (The 50 mcg tablet is formulated without color additives for patients who are sensitive to dyes.) There is no well-documented evidence of true allergic or idiosyncratic reactions to thyroid hormone. SYNTHROID is also contraindicated in the patients with uncorrected adrenal insufficiency, as thyroid hormones increase tissue demands for adrenocortical hormones and may thereby precipitate acute adrenal crisis (see **PRECAUTIONS**).

WARNINGS Thyroid hormones, either alone or together with other therapeutic agents, should not be used for the treatment of obesity. In euthyroid patients, doses within the range of daily hormonal requirements are ineffective for weight reduction. Larger doses may produce serious or even life threatening manifestations of toxicity particularly when given in association with sympathomimetic amines such as those used for their anorectic effects.

The use of SYNTHROID in the treatment of obesity, either alone or in combination with other drugs, is unjustified. The use of SYNTHROID is also unjustified in the treatment of male or female infertility unless this condition is associated with hypothyroidism.

PRECAUTIONS General SYNTHROID should be used with caution in patients with cardiovascular disorders, including angina, coronary artery disease, and hypertension, and in the elderly who have a greater likelihood of occult cardiac disease. Concomitant administration of thyroid hormone and sympathomimetic agents to patients with coronary artery disease may increase the risk of coronary insufficiency.

Use of SYNTHROID in patients with concomitant diabetes mellitus, diabetes insipidus or adrenal cortical insufficiency may aggravate the intensity of their symptoms. Appropriate adjustments of the various therapeutic measures directed at these concomitant endocrine diseases may therefore be required. Treatment of myxedema coma may require simultaneous administration of glucocorticoids (see **DOSAGE AND ADMINISTRATION**).

T_4 enhances the response to anticoagulant therapy. Prothrombin time should be closely monitored in patients taking both SYNTHROID and oral anticoagulants, and the dosage of anticoagulant adjusted accordingly.

Seizures have been reported rarely in association with the initiation of levothyroxine sodium therapy, and may be related to the effect of thyroid hormone on seizure threshold.

Lithium blocks the TSH-mediated release of T_4 and T_3. Thyroid function should therefore be carefully monitored during lithium initiation, stabilization, and maintenance. If hypothyroidism occurs during lithium treatment, a higher than usual SYNTHROID dose may be required.

Laboratory Tests Treatment of patients with SYNTHROID requires periodic assessment of adequacy of titration by appropriate laboratory tests and clinical evaluation. Selection of appropriate tests for the diagnosis and management of thyroid disorders depends on patient variables such as presenting signs and symptoms, pregnancy, and concomitant medications. A combination of sensitive TSH assay and free T_4 estimate (free T_4, free T_4 index) are recommended to confirm a diagnosis of thyroid disease. Normal ranges for these parameters are age-specific in newborns and younger children.

TSH alone or initially may be useful for thyroid disease screening and for monitoring therapy for primary hypothyroidism as a linear inverse correlation exists between serum TSH and free T_4. Measurement of total serum T_4 and T_3, resin T_3 uptake, and free T_3 concentrations may also be useful. Antithyroid microsomal antibodies are an indicator of autoimmune thyroid disease. The presence of positive microsomal antibodies in an euthyroid patient is a major risk factor for the future development of hypothyroidism. An elevated serum TSH in the presence of a normal T_4 may indicate subclinical hypothyroidism. Intracellular resistance to thyroid hormone is quite rare, and is suggested by clinical signs and symptoms of hypothyroidism in the presence of high serum T_4 levels. Adequacy of SYNTHROID therapy for hypothyroidism of pituitary or hypothalamic origin should be assessed by measuring free T_4 which should be maintained in the upper half of the normal range. Measurement of TSH is not a reliable indicator of response to therapy for this condition. Adequacy of SYNTHROID therapy for congenital and acquired pediatric hypothyroidism should be assessed by measuring serum total T_4 or free T_4, which should be maintained in the upper half of the normal range. In congenital hypothyroidism, normalization of serum TSH levels may lag behind normalization of serum T_4 levels by 2 to 3 months or longer. In rare patients serum TSH remains relatively elevated despite clinical euthyroidism and age-specific normal levels of T_4 or free T_4.

Drug Interactions The magnitude and relative clinical importance of the effects noted below are likely to be patient-specific and may vary by such factors as age, gender, race, intercurrent illnesses, dose of either agent, additional concomitant medications, and timing of drug administration. Any agent that alters thyroid hormone synthesis, secretion, distribution, effect on target tissues, metabolism, or elimination may alter the optimal therapeutic dose of SYNTHROID.

Adrenocorticoids–Metabolic clearance of adrenocorticoids is decreased in hypothyroid patients and increased in hyperthyroid patients, and may therefore change with changing thyroid status.

Amiodarone–Amiodarone therapy alone can cause hypothyroidism or hyperthyroidism.

Anticoagulants (oral)–The hypoprothrombinemic effect of anticoagulants may be potentiated, apparently by increased catabolism of vitamin K-dependent clotting factors.

Antidiabetic agents (insulin, sulfonylureas)–Requirements for insulin or oral antidiabetic agents may be reduced in hypothyroid patients with diabetes mellitus, and may subsequently increase with the initiation of thyroid hormone replacement therapy.

β-adrenergic blocking agents–Actions of some beta-blocking agents may be impaired when hypothyroid patients become euthyroid.

Cytokines (interferon, interleukin)–Cytokines have been reported to induce both hyperthyroidism and hypothyroidism.

Digitalis glycosides–Therapeutic effects of digitalis glycosides may be reduced. Serum digitalis levels may be decreased in hyperthyroidism or when a hypothyroid patient becomes euthyroid.

Ketamine–Marked hypertension and tachycardia have been reported in association with concomitant administration of levothyroxine sodium and ketamine.

Maprotiline–Risk of cardiac arrhythmias may increase.

Sodium iodide (^{123}I and ^{131}I), sodium pertechnetate $Tc99m$–Uptake of radiolabeled ions may be decreased.

Somatrem/somatropin—Excessive concurrent use of thyroid hormone may accelerate epiphyseal closure. Untreated hypothyroidism may interfere with the growth response to somatrem or somatropin.

Theophylline—Theophylline clearance may decrease in hypothyroid patients and return toward normal when a euthyroid state is achieved.

Tricyclic antidepressants—Concurrent use may increase the therapeutic and toxic effects of both drugs, possibly due to increased catecholamine sensitivity. Onset of action of tricyclics may be accelerated.

Sympathomimetic agents—Possible increased risk of coronary insufficiency in patients with coronary artery disease.

Laboratory Test Interactions A number of drugs or moieties are known to alter serum levels of TSH, T_4 and T_3 and may thereby influence the interpretation of laboratory tests of thyroid function (see **Drug Interactions**):

1. Changes in TBG concentration should be taken into consideration when interpreting T_4 and T_3 values. Drugs such as estrogens and estrogen-containing oral contraceptives increase TBG concentrations. TBG concentrations may also be increased during pregnancy and in infectious hepatitis. Decreases in TBG concentrations are observed in nephrosis, acromegaly, and after androgen or corticosteroid therapy. Familial hyper- or hypo-thyroxine-binding-globulinemias have been described. The incidence of TBG deficiency is approximately 1 in 9000. Certain drugs such as salicylates inhibit the protein-binding of T_4. In such cases, the unbound (free) hormone should be measured. Alternatively, an indirect measure of free thyroxine, such as the FT_4I may be used.

2. Medicinal or dietary iodine interferes with *in vivo* tests of radioiodine uptake, producing low uptakes which may not indicate a true decrease in hormone synthesis.

3. Persistent clinical and laboratory evidence of hypothyroidism despite an adequate replacement dose suggests either poor patient compliance, impaired absorption, drug interactions, or decreased potency of the preparation due to improper storage.

Carcinogenesis, Mutagenesis, and Impairment of Fertility: Although animal studies to determine the mutagenic or carcinogenic potential of thyroid hormones have not been performed, synthetic T_4 is identical to that produced by the human thyroid gland.

A reported association between prolonged thyroid hormone therapy and breast cancer has not been confirmed and patients receiving levothyroxine sodium for established indications should not discontinue therapy.

Pregnancy: Pregnancy Category A. Studies in pregnant women have not shown that levothyroxine sodium increases the risk of fetal abnormalities if administered during pregnancy. If levothyroxine sodium is used during pregnancy, the possibility of fetal harm appears remote. Because studies cannot rule out the possibility of harm, levothyroxine sodium should be used during pregnancy only if clearly needed.

Thyroid hormones cross the placental barrier to some extent. T_4 levels in the cord blood of athyroid fetuses have been shown to be about one-third of maternal levels. Nevertheless, maternal-fetal transfer of T_4 may not prevent *in utero* hypothyroidism.

Hypothyroidism during pregnancy is associated with a higher rate of complications, including spontaneous abortion and preeclampsia, and has been reported to have an adverse effect on fetal and childhood development. On the basis of current knowledge, SYNTHROID® (levothyroxine sodium, USP) should therefore not be discontinued during pregnancy, and hypothyroidism diagnosed during pregnancy should be treated. Studies have shown that during pregnancy T_4 concentrations may decrease and TSH concentrations may increase to values outside normal ranges. Postpartum values are similar to preconception values. Elevations in TSH may occur as early as 4 weeks gestation.

Pregnant women who are maintained on SYNTHROID should have their TSH measured periodically. An elevated TSH should be corrected by an increase in SYNTHROID dose. After pregnancy, the dose can be decreased to the optimal preconception dose.

Nursing Mothers Minimal amounts of thyroid hormones are excreted in human milk. Thyroid hormones are not associated with serious adverse reactions and do not have known tumorigenic potential. While caution should be exercised when SYNTHROID is administered to a nursing woman, adequate replacement doses of levothyroxine sodium are generally needed to maintain normal lactation.

Pediatric Use: Congenital hypothyroidism Rapid restoration of normal serum T_4 concentrations is essential for preventing the deleterious effects of neonatal thyroid hormone deficiency on intelligence, as well as on overall growth and development. SYNTHROID should be initiated immediately upon diagnosis, and is generally continued for life. The goal of therapy is to maintain the serum total T_4 or FT_4 in the upper half of the normal range and serum TSH in the normal range.

An initial starting dose of 10 to 15 mcg/kg/day (ages 0-3 months) will generally increase serum T_4 concentrations to the upper half of the normal range in less than 3 weeks. Clinical assessment of growth and development and thyroid status should be monitored frequently. In most cases, the dose of SYNTHROID per body weight will decrease gradually as the patient grows through infancy and childhood (see Table). Prolonged use of large doses in infants may be associated with later behavior problems.

Thyroid function tests (serum total T_4 or FT_4, and TSH) should be monitored closely and used to determine the adequacy of SYNTHROID therapy. Normalization of serum T_4 levels is usually followed by a rapid decline of TSH levels. Nevertheless, normalization of TSH may lag behind normalization of T_4 levels by 2 to 3 months or longer. The relative elevation of serum TSH is more marked during the early months of therapy, but can persist to some degree throughout life. In rare patients TSH remains relatively elevated despite clinical euthyroidism and age-specific normal levels of total T_4 or FT_4. Increasing the SYNTHROID dosage to suppress TSH into the normal range may result in overtreatment, with an elevated serum T_4 level and clinical features of hyperthyroidism, including irritability, increased appetite with diarrhea, and sleeplessness. Another risk of prolonged overtreatment in infants is premature cranial synostosis.

Assessment of permanence of hypothyroidism may be done when transient hypothyroidism is suspected. Levothyroxine therapy may be interrupted for 30 days after 3 years of age and serum measurement of T4 and TSH levels obtained. If T_4 is low and the TSH level is elevated, permanent hypothyroidism is confirmed and therapy should be re-instituted. If T_4 and TSH remain in the normal range, a presumptive diagnosis of transient hypothyroidism can be made. In this instance, continued clinical monitoring and periodic reevaluation of thyroid function may be warranted.

Acquired hypothyroidism. The initial dose of SYNTHROID varies with age and body weight, and should be adjusted to maintain serum total T_4 or free T_4 levels in the upper half of the normal range. In general, in the absence of overriding clinical concerns, children should be started on a full replacement dose. Children with underlying heart disease should be started at lower doses, with careful upward titration. Children with severe, long-standing hypothyroidism may also be started on a lower initial dose with upward titration in an attempt to avoid premature closure of epiphyses. The recommended dose per body weight decreases with age (see Table).

Treated children may resume growth at a rate greater than normal (period of transient catch-up growth). In some cases catch-up growth may be adequate to normalize growth; however, in children with severe and prolonged hypothyroidism, adult height may be reduced. Excessive thyroxine replacement may initiate accelerated bone maturation resulting in disproportionate advancement in skeletal age and shortened adult stature.

Assessment of permanence of hypothyroidism may be done when transient hypothyroidism is suspected. Levothyroxine therapy may be interrupted for 30 days and serum measurement of T_4 and TSH levels obtained. If T_4 is low and the TSH level is elevated, permanent hypothyroidism is confirmed and therapy should be re-instituted. If T_4 and TSH remain in the normal range, a presumptive diagnosis of transient hypothyroidism can be made. In this instance, continued clinical monitoring and periodic reevaluation of thyroid function may be warranted.

ADVERSE REACTIONS Adverse reactions other than those indicative of thyrotoxicosis as a result of therapeutic overdosage, either initially or during the maintenance periods, are rare (see **OVERDOSAGE**). Craniosynostosis has been associated with iatrogenic hyperthyroidism in infants receiving thyroid hormone replacement therapy. Inadequate doses of SYNTHROID may produce or fail to resolve symptoms of hypothyroidism. Hypersensitivity reactions to the product excipients, such as rash and urticaria, may occur. Partial hair loss may occur during the initial months of therapy, but is generally transient. The incidence of continued hair loss is unknown. Pseudotumor cerebri has been reported in pediatric patients receiving thyroid hormone replacement therapy.

OVERDOSAGE: Signs and Symptoms: Excessive doses of SYNTHROID result in a hypermetabolic state indistinguishable from thyrotoxicosis of endogenous origin. Signs and symptoms of thyrotoxicosis include weight loss, increased appetite, palpitations, nervousness, diarrhea, abdominal cramps, sweating, tachycardia, increased pulse and blood pressure, cardiac arrhythmias, tremors, insomnia, heat intolerance, fever, and menstrual irregularities. Symptoms are not always evident or may not appear until several days after ingestion.

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The closing date for classified advertising is the first day of the month preceding the month of the issue. Ads are free for current NCPhA members, if indicated when placing the ad. The non-member rate is .50¢ a word with a $10 minimum. Send ads to Carolina Journal of Pharmacy, c/o NCPhA, P.O. Box 229, Chapel Hill, NC 27514-0229 or fax to 919-968-9430.

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- The new header record required for NC Medicaid Batch electronic billing to EDS has been implemented.
- The patient now may be indicated as EXEMPT from the limit of six if you have a letter on file.
- Diagnosis codes were added to the patient record.
- The ability to build sigs from partial sigs and whole words intermixed was added.
- Security measures were added to prevent charging to unauthorized customers.
- Multiple third parties may be added to the customer record and the primary third party serves as the default. Secondary third parties may be billed in batch or individually by indicating the prescription numbers and dates.

  When billing a second third party such as Medicaid, you may indicate what the other payor amount was. The new rebilling function makes retroactive Medicaid billing a cinch.
- The entire MediSpan drug file (total file) was added. This file is updated and added to each week. You can add new drugs to your system drug file anytime you wish, even during a refill, by typing in the new NDC and the drug will be instantly pulled from the total file.
- Multiple user-defined tax rates were added.
- Acquisition drug costs now appear on the prescription filling screen.
- Date of activity is tracked so drugs that are not being used can be deleted easily.
- Prescribers can be listed with other prefixes such as PA, NP, etc.

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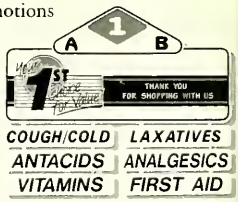

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Voice and Vision

Daniel Garrett, Executive Director

"If you have built castles in the air, your work need not be lost. That is where they should be. Now put the foundations under them."

Henry David Thoreau

We are now in the age of information. The industrial age is gone. Pharmacists have a choice, we can join this new age or become a memory. Pharmacy leaders from all areas of practice in North Carolina have decided to move forward. In the spirit of the founding purpose of NCPhA in 1880, there is unanimous support in 1998 to "*unite, serve and advance*" the profession: our collective goal is One Voice, One Vision-2000. To serve the needs of the public in the information age, we must firmly establish our role as providers of pharmacy knowledge by forming one organization to clearly share our purpose.

The responsibility for transformation of our profession is ours collectively. My personal responsibility will be to serve as your voice and to share your vision. I believe that the source of authority of a leader comes from the ability of the leader to serve the needs of those who follow. Every other month I will use this column to let you know what I am hearing from you and offer my perspective on the Voice and Vision of pharmacy.

This journal contains descriptions of the castles you are building and what foundations are required to support them. This is a landmark issue of the Carolina Journal of Pharmacy. It is our largest ever and marks the inclusion of the newsletter of the North Carolina Society of Health-System Pharmacists. The outcomes of the activities of the North Carolina Center for Pharmaceutical Care are reported in the article on the Asheville Project. The results of the Asheville Project represent the collective leadership of all pharmacy organizations in our state which began four years ago.

The annual convention for NCPhA is featured and new president Keith Elmore's remarks reflect the spirit of unity present at the meeting. An article on NCCPC's leadership retreat reflects the spirit of young pharmacy leaders who are emerging across our state. A report on how pharmacists are working with their communities to meet the needs of indigent care clinics affirms our commitment to help the less fortunate in our society. Asthma Awareness Month is on the horizon and is a great opportunity for pharmacists to demonstrate our value by working collaboratively with other health care providers.

Margaret Booth's award winning student essay on the future of pharmacy is timely in this issue of the Journal. She paints a picture of pharmacy in the information age which is realistically prophetic. Margaret boldly states her vision of where pharmacy "is" going and in a clear voice states, "The only way we will get there is continued education, unification and persistence. It is exciting to think of the opportunities that await. We all should leap forward with both feet first."

North Carolina Pharmacy is taking action to fulfill Margaret Booth's predictions. A continuing education summit was held on June 8th, and as a result of input from the AHECs, UNC, Campbell, Duke, NCSHP and NCPhA, it was agreed that UNC and NCPhA will share a statewide Pharmacy CE Coordinator. Steve Caiola will serve in this new position and work with organizational pharmacy to develop a strategic plan for local, state and certificate programs. The NCPhA and NCSHP boards have approved hiring a consultant to facilitate the One Voice, One Vision merger process which will also include the retail and consultant pharmacist groups. A meeting was held on June 19th to initiate the formation of a statewide pharmacist network for reimbursement for disease management.

The NCPhA staff is working to develop a three-year plan to implement pharmacy's new organizational structures and networks.

We have begun building the *vision* for our new castles for pharmacy and these pages are the *voice* on how to put foundations under them.

Diabetes educator Mary Beth Horrell, MS, RD, CDE, at the Mission St. Joseph's Diabetes Center asks one of her students about her self-care routine.

The Asheville Project

by Scotti Kent

Members of the North Carolina Center for Pharmaceutical Care (NCCPC) have long believed that by working with community resources, pharmacists can enhance physicians' efforts, improve the health of patients and save money for payers. Now, the City of Asheville Diabetes Management Project is proving their point.

In early 1997, NCCPC, a coalition of state pharmacy organizations, teamed with Mission St. Joseph's Health System in Asheville, N.C., local pharmacies and the City of Asheville to conduct a yearlong study on the impact pharmacists can have on disease management. By May of 1997, a group of specially trained pharmacists began counseling diabetes patients insured by the City.

When NCCPC leaders began formulating plans for the pilot program in 1995, they were operating from three strong beliefs.

1. Pharmacists can make a significant contribution to the health-care delivery system by playing an expanded role in disease management.

2. By working proactively with patients to improve their health, especially those with chronic diseases, pharmacists become much more than dispensers of medications, they become counselors, clinical educators and patient advocates. They also become valuable partners with other providers of health care.

3. Third-party payers who include pharmacists in the health-care loop to offer these amplified services will discover that their costs are substantially reduced.

Dan Garrett, MS, RPh, president of NCCPC, shares outcomes with Asheville Project participants.

As part of a 12-month follow-up, Phyllis Sherrill, of Asheville, has her hemoglobin A1C levels checked by Cynthia Boyd, CNA.

The Asheville Project - Summary of Findings

The study shows pharmacists can have significant impact on health management.

Baseline data collected in May 1997 has been compared with information gathered six months into the project. The results are significant:

Table 1. Quality of Life: Improved
The majority of the participants reported improvements in physical, mental and social function, pain, energy level and overall health. (Measurement Tool: SF-36 health status tool. The terms "role physical" and "role emotional" refer to participants' perceptions of their ability to perform the daily activities they want or need to perform, including the ability to handle stress.)

Table 2. Lab Values: Improved
The results of lab tests show significant improvement in most of the participants' hemoglobin A1C, triglyceride and cholesterol levels. The one exception was HDL, which increased over the baseline for 44 percent of the participants, but decreased for 52 percent.

Table 3. Patient Satisfaction with Pharmacy: Improved
Surveys showed that participants' overall satisfaction with their pharmacy has increased, as well as satisfaction with key areas such as:
• explanation (a measure of how satisfied patients were with the pharmacists' explanation of drug therapy, side effects, etc.)
• consideration (an indicator of how courteous the pharmacy staff was)
• technical competence (an indicator of patients' confidence in the technical ability of the pharmacist)

Table 4. Costs to Payer: Reduced
For an investment of around $14,000, the City of Asheville's health plan saved more than $25,000 in the first six months of the project. Properly managing diabetes also helps prevent the development of much more serious — and costly — health problems like heart disease, renal failure and blindness.

The patient satisfaction survey instrument was based on information provided in the following articles:

MacKeigan LD, Larson LN. Development and validation of an instrument to measure patient satisfaction with pharmacy services. Med Care. 1989; 27:522-36.

Larson LN, MacKeigan LD. Further validation of an instrument to measure patient satisfaction with pharmacy services. J of Pharmaceutical Marketing & Management. 1994; 8(1):125-139.

Domains used were those demonstrated by MacKeigan and Larson to be most reliable and to have acceptable internal consistency. All items questioned patients about their satisfaction on a five-point Likert scale (Strongly Agree to Strongly Disagree).

Table 1 — Quality of Life

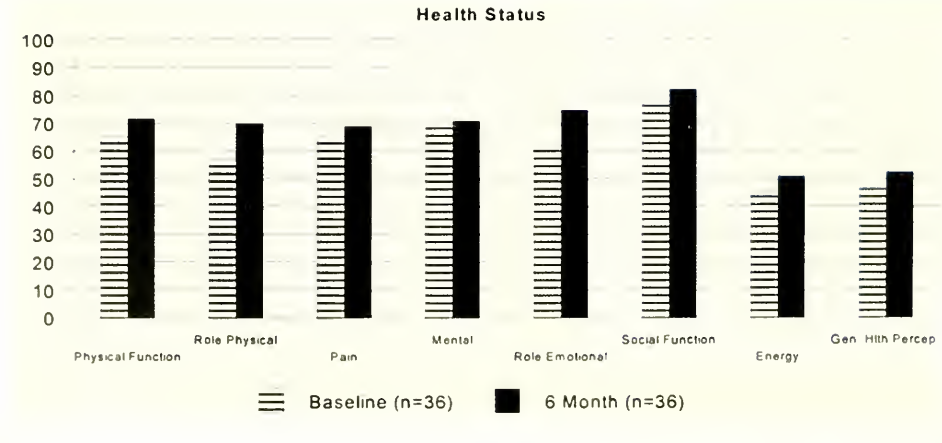
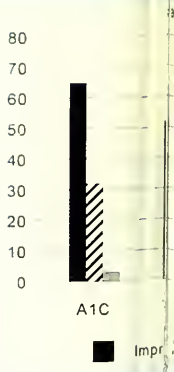


Table 2 — Lab Valu



Moving On

NCCPC has been invited to share its findings with HCFA (Health Care Financing Administration), representatives from Medicaid and the City of Raleigh, N.C. In March, Daniel Garrett, RPh, and John Miall, risk management director for the City of Asheville, updated City Council on the results of the study. Their report met with a favorable response.

"I am very supportive of this element of the City's disease-management program," said Asheville Mayor Leni Sitnick. "It is a true partnership between the City, local pharmacists and a segment of employees with certain health problems. It is another opportunity for us to provide a positive health benefit for our employees."

At their final progress checkup for the study, participants were told that the City of Asheville has decided to continue to fund pharmaceutical care for the individuals who participated.

"The greatest credit for the changes and improvements shown by this data belongs not to me, not to the pharmacists or the physicians, but to you," Garrett, president of the NCCPC, told the group. "You're the ones who made a commitment to stick yourselves two, three or four times a day, knowing that the printout will show if you've had an 'eating indiscretion.' You're the ones who have to exercise, who have to make sure the food you eat is the right food and who have to make sure you take your medicine and give yourself insulin. The credit goes to you, because you're the ones in control of your lives."

The project has been so successful for people with diabetes, a second study is already underway involving asthma patients who work for the City of Asheville.

Overall Plan Impact

Costs: July 1, 1996 to Dec. 31, 1996 —	$87,363.13
Costs: July 1, 1997 to Dec. 31, 1997 —	$61,846.57*
DIFFERENCE TO PLAN FOR GROUP CONTROL PERIOD VS. TEST PERIOD	+ $25,516.56

* NOTE: During July 1, 1997 through Dec. 31, 1997 test period, one participant diagnosed with leukemia had costs of $15,199.82 ($9,156.05 higher than control period.)

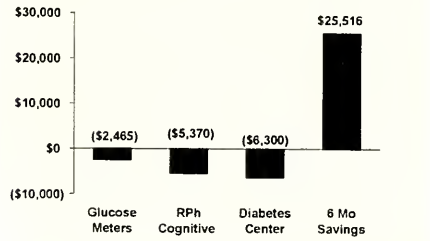
Retiree Group — Medical Cost Comparison

The City of Asheville's health plan is somewhat unusual in that it continues to cover employees after retirement. With this population in particular, disease management and prevention are of critical importance. A comparison of costs for retirees between July 1 and Dec. 31, 1997, shows a significant improvement over the same period in 1996.

Costs: July 1, 1996 to Dec. 31, 1996 — $59,682 (68%)
Costs: July 1, 1997 to Dec. 31, 1997 — $34,688 (56%)
RETIREE GROUP SAVINGS..... + $24,999 (97%)

Table 4

Program Costs & Savings



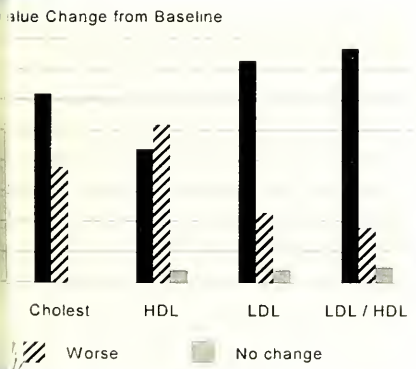
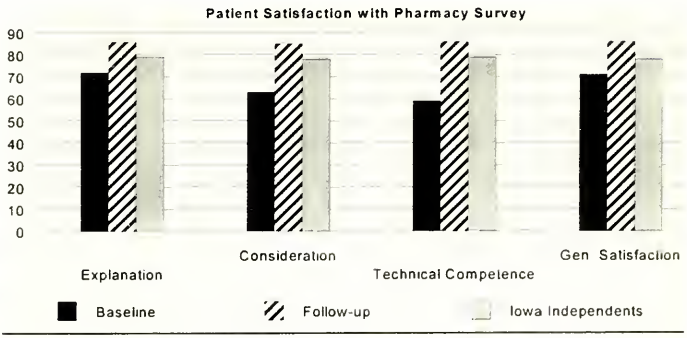


Table 3 — Patient Satisfaction with Pharmacy



(100% = perfect satisfaction in each domain. Mean scores for N=35 patients.)

The Asheville Project — Training

"We knew that a key factor in the success of the City of Asheville Diabetes Project was preparing the pharmacists," said Dan Garrett. "In our community, doctors and pharmacists aren't the only people involved in diabetes care. The Diabetes Center associated with Mission St. Joseph's Health System offers education and support to people with diabetes and their families, so we formed an alliance with them early on. The medical director for The Diabetes Center is an endocrinologist. We began working with him, and the center's director and staff, who are certified diabetes educators, to put together a training program for the pharmacists."

Faculty members from the schools of pharmacy at the University of North Carolina at Chapel Hill and from Campbell University in Buies Creek were enlisted to assist with the training, as well as Diabetes Center staff members and Asheville physicians. Ultimately, eighteen faculty and presenters took part in the intensive training sessions which were provided for the pharmacists over two weekends in January of 1997, just a few months before the Asheville Project began.

Weaverville Drug Co. has the look and feel of the old days, but the pharmaceutical care offered by Chuck Sprinkle, RPh, is leading the way to better outcomes for people with chronic illnesses like diabetes.

The Training Program

According to Cindy Spillers, MS, RD, CDE, director of The Diabetes Center, the goals of the training program were to enable the pharmacists to update their knowledge of diabetes and management issues (including disease monitoring), diabetes-related products and prescription and nonprescription medications taken by people with diabetes. The format included lectures, group discussions and, perhaps most importantly, hands-on experiences.

"We felt that the pharmacists needed a lot of practical, hands-on training, not only to reinforce the basic education, but to enable them to be supportive of the patients as well," Spillers said.

During the training, the pharmacists performed many of the tasks that people with diabetes must perform on a daily basis to discover what it's like to be 'in their shoes' and to learn how much dexterity and visual acuity are necessary to carry out these tasks. They pricked their fingers and used blood glucose monitors to test their own blood sugar levels, learned to inject themselves — using saline rather than insulin — and ate snacks and meals throughout the two weekends that would be recommended for people with diabetes."

Stephanie Kiser, RPh, found this practical training particularly helpful. "I worked with people with diabetes for several years when I was with the Indian Health Service, and as a hospital-based pharmacist with Memorial Mission Hospital for three years, so a lot of the basic information was a review for me," she said. "But I learned a great deal from the hands-on work that we did."

Phil Crouch, RPh, who sees eleven of the Asheville Project patients at Kerr Drug in Asheville, agreed with Kiser. "The training classes really benefitted me in terms of learning how to use a variety of blood glucose monitors, not just the one we sell in our store," he said. "And learning the specifics - the hows and whys - about diet and exercise has especially helped me work with the patients. Whereas a patient might have simply been told to exercise because it will help him, now I can go into details with him and explain *how much* exercise, *what kind* of exercise and exactly why it will improve his condition. I've even shared some of the recipes we were given with the patients. The food was very good. I was surprised!"

The Faculty

Six physicians from the Asheville community who work with people with diabetes were invited to present lectures and share information with the pharmacists: a nephrologist, a retinal specialist, an endocrinologist, a cardiologist, an orthopedic who sees a number of patients with diabetes-related foot problems and a pediatric endocrinologist.

In addition to participating in the training sessions, these six physicians were also helpful as NCCPC established protocols for the pharmacists regarding when to contact a patient's physician. "We asked the doctors to tell us what problems they would want to be called about," said Garrett. "They helped us come up with a check list covering these situations, prioritized according to urgency. We wanted clear communication channels to be established, and with the help of these key physicians from the outset, I believe we accomplished that. Their input was invaluable."

Six members of The Diabetes Center made significant contributions to the training program. For example, the center's certified clinical social worker explained how stress can affect patients with diabetes and their families. Other certified diabetes educators and specialists on staff lectured on topics such as exercise, nutrition and meal planning, and how to teach patients. They also conducted the hands-on classes on insulin administration (devices and techniques) and blood glucose monitor techniques.

The remaining faculty and presenters were pharmacists from NCCPC and from the two universities. Their tasks were to review current pharmacotherapy treatment strategies for diabetes, contraindications, how other medications may impact blood sugar, etc.

Measuring Success

Based on the verbal feedback from the 24 pharmacists who went through the training, Spillers and the NCCPC representatives felt that the program had been successful. But they administered a test following the training to make sure.

"The pharmacists were given a 'pretest' and a 'post-test,'" Spillers said. "We wanted to see how much they knew before the two weekend intensives, and then how much they knew at the end. Basically, the tests showed that they definitely improved ... pretty dramatically!

"We are glad that NCCPC included us in the Asheville Project," she said. "It was a perfect fit for us. As the diabetes education center in this area, we want to be recognized as a resource."

The pharmacists were also asked to encourage patients to attend programs at The Diabetes Center, especially if they had not had diabetes self-management training in the past. Frequent hypoglycemia, wide fluctuations in blood glucose readings, poor understanding of meal planning, sick day self-management and foot care were also listed as indications for referral to the Center.

"A chronic illness like diabetes requires a lot of self-management," said endocrinologist Jeff Russell, MD, Medical Director for The Diabetes Center. "Pharmacists educated and trained in managing that specific health problem can make a tremendous difference by monitoring people with diabetes and encouraging them to follow through on self-care."

A popular feature of the Medicap Pharmacy in Black Mountain, N.C. is its timesaving drive-up window. Inside, Ruth Higgins, RPh, spends as much time as needed to counsel and educate participants in the Asheville Project.

The Pharmacist's Role — Pharmaceutical Care in Action

When Bill Horton, RPh, talks to his fellow pharmacists about pharmaceutical care like that provided to participants in the Asheville Project, he stresses several key points:

- The concept of "pharmaceutical care" is not new.
- Pharmacists need to take a fresh look at their practices and find the means to shift emphasis from the commodity to the cognitive side of practice.
- Pharmacists should participate in disease management only under protocol coordinated with a referring physician. A team approach is central to the success of pharmaceutical care.
- It is essential for pharmacists to receive appropriate training and education on diseases they expect to help manage, and to maintain their expertise. Objective certification lends credibility and an assurance that adequate training has taken place.
- Written policies and procedures must be used consistently for all specialized services such as drug monitoring, disease monitoring and disease management.
- By networking with each other, pharmacists can establish standards for pharmaceutical care programs. They can then negotiate with payers in a consistent manner with respect to charges, reimbursement and potential savings to the payer.

"The pharmacist's role is to spend in-depth 'quality' time with people, one-on-one, to monitor and help them manage their own health," said Horton. "We may also provide information to a person's physician about drug interaction or make suggestions if a particular form of drug therapy fails. We alert the physician if someone is not taking their medication as prescribed. Our goal is to help individuals manage their disease through life-style changes that only they can make."

Pharmacists involved in the Asheville Project follow specific steps in working with people who have diabetes. These are outlined briefly below.

Training and Education

Obtain education and training from experts. Topics should include:

- pathophysiology
- appropriate therapies (nutritional, pharmacotherapy, exercise, stress management, monitoring)
- current concepts in oral therapy including combination and oral/insulin
- current concepts in insulin therapy
- workshops on insulin administration and blood glucose monitoring
- how to use a team approach to provide self-management patient education and training including devices

(continued on page 11)

NCCPC Hosts Seminar at Highland Lake Inn

Mollie Ashe Scott, PharmD, BCPS, Assistant Professor of Pharmacy Practice, Campbell University School of Pharmacy and Michelle Fritsch, PharmD, Assistant Professor of Pharmacy Practice, Campbell University School of Pharmacy

The North Carolina Center for Pharmaceutical Care (NCCPC) hosted an innovative seminar in April at the Highland Lake Inn Country Retreat in Flat Rock, N.C. Bayer Pharmaceuticals sponsored the three-day retreat. Dan Garrett, president of NCCPC, sought to bring North Carolina pharmacists together to discuss advancement of pharmaceutical care. Approximately 25 pharmacists from across the state participated in the program. These pharmacists represented diverse practice areas including hospital pharmacy, community pharmacy, managed care and academia. NCCPC plans to conduct similar seminars across the state.

The participants completed the Drake Personality Profile prior to attending the meeting and received an individual report that described their personality style during the program. Phil Milam from Bayer Pharmaceuticals led a lively discussion on development of successful interactions with colleagues who have different personality types.

Stephanie Barnard from Bayer Pharmaceuticals presented a seminar on "Writing and Speaking for Excellence." Her valuable tips for improving business writing and professional speaking stimulated much discussion.

Laura Smith, Elizabeth Michelets and Anna Garrett shared their experiences with reimbursement for cognitive services. Dr. Smith and Dr. Michelets described how outpatient and inpatient pharmacists at Mission St. Joseph's Health Systems in Asheville are billing for activities such as patient education, disease state management, nutrition support and pharmacokinetics consults. Dr. Garrett described how to establish pharmaceutical care services in an HIV clinic and explored potential barriers to reimbursement in such an environment. Participants shared their experiences billing for cognitive services in their practices during a round table discussion.

After identifying challenging obstacles in pharmacy practice, pharmacists participated in small group discussions on problem resolution. Some areas of focus included motivation of coworkers, increasing effectiveness in the workplace, handling conflict, increasing leadership, prioritizing responsibilities and developing a team approach to pharmaceutical care.

Throughout the seminar series, Dan Garrett challenged the participants to examine their personal spirits and to carry on the story of quality pharmacy practice into the next century.

Preliminary 1-year results for 33 of 43 employees of the City who have diabetes and are enrolled in a wellness program being conducted in cooperation with the City of Asheville, Campbell and UNC Schools of Pharmacy and the North Carolina Center for Pharmaceutical Care. Fifteen Asheville-area pharmacists received additional training in monitoring diabetes patients, and they are involved in the outcomes study being conducted to determine if pharmacists can help improve patients' compliance with their medications, improve their understanding of their disease and contribute to improved blood glucose control.

12-Month Results

- 30 of 33 (91%) have improvment of HgbA1C at 1 year
- 12 of 33 (36%) had a HgbA1C within normal range at baseline (lab range for normal 4.4-6.4%)
- 23 of 33 (70%) have HgbA1C within normal range at 1 year
- DCCT found that for every decline of 1% in a group's average HgbA1C (~30mg/dl avg. blood glucose) the risk reduction is:
  - 76% decreased risk of retinopathy
  - 60% decreased risk of neuropathy
  - 50% decreased risk of nephropathy
  - 41 % decreased risk of heart disease
- HgbA1C average for Asheville group was lowered by 1.4%

Why is this working?
STRUCTURED ACCOUNTABILITY with FINANCIAL INCENTIVES

At Kerr Drug in Asheville, Phil Crouch, RPh, is a perfect example of how large chain drug stores can offer personalized, user-friendly services that help people improve their health.

• pathology of long-term complications - signs, symptoms, treatment and prevention

• workshops and methods for improving counseling skills

• how to perform a patient assessment interview and determine further patient education needs based on a plan developed from the interview

• how to document pharmacist care using FARM (Finding, Assessment, Recommendation, Monitoring) note format

• practice with case studies using the FARM format

Patient Communication

In addition to receiving training on the management of diabetes, pharmacists participating in the Asheville Project have been testing "Patient Communication Insights," a computer software program that offers "a quick and inexpensive method to assess behavioral characteristics that influence patients' actions in a medical setting." Patients complete a one-page personality preference questionnaire and the information is entered into the computer by the pharmacist.

Based on these personality characteristics, the program provides "tips" to the care giver on how to increase that individual's level of trust and compliance. "Patient Communication Insights" is being co-marketed by the North Carolina Pharmaceutical Association and Health Care Insights.

Physical Preparation

• Set up a well-stocked diabetes department and familiarize yourself with the products.

• Provide a separate area for counseling.

• Design your work schedule to include uninterrupted time for counseling sessions.

• Set up a filing system for documentation.

• Prepare copies of handouts and forms.

The Initial Consultation

• If the person is not familiar with the service being provided, help them understand what you hope to accomplish together.

• Take a detailed history using standard forms provided for that purpose.

• Learn as much as you can about what communication style will work best with a particular individual.

• Help the person set goals regarding life-style changes he or she would like to make.

• Provide any necessary training, such as how to use a glucose meter or how to mix insulin.

• Record and document everything in a standard format such as FARM or SOAP (Subjective and Objective findings, Assessment and treatment Plan)

• Plan follow-up visits. These should take place at least once a month.

Physician Communication

• Let the person's physician know that you have met with the person and what you hope to accomplish.

• Ask the physician to tell you if he or she has any special orders, instructions or goals for the person. It may be helpful to actually list the most likely areas with respect to the particular disease being managed. For diabetes, this list might include how often to monitor blood glucose, diet, exercise, blood sugar goals, weight, lipids, blood pressure, smoking and alcohol use.

Lord's Drug in Asheville offers "one stop shopping" with its convenient location inside a supermarket. Kim Ferguson, RPh, provides "food for thought" to people with diabetes seeking to better manage their health.

• Assure the physician that you will follow-up regularly with him or her.

Follow-Up Meetings

• Build on what has already been learned and provide additional training or review past education.

• Monitor the person's blood sugar levels over the past month.

• Ask about problems or questions the person may have.

• Document the meeting.

"Often, just knowing that they are being monitored is an incentive to people," Horton said. "I tell people this is a team approach — and you are the most important member of the team."

"We pharmacists all like to say we are committed to helping people," he said. "And indeed, that is the public's perception of our profession. We have an opportunity to put our education and experience to a higher use by becoming an integral part of a team dedicated to improving health care and improving disease outcomes. Every technique and approach we have used towards diabetes in the Asheville Project can be used effectively for management of asthma, hypertension, hyperlipidemia and many other chronic conditions."

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Report of NCPhA Task Force on Membership

Introduction: The Task Force on Membership, appointed by President Jimmy Jackson, was asked to consider various options for having a single organization representing pharmacy in North Carolina. The current situation where pharmacy is fragmented into many voices and organizations is seen by many as reducing our ability to achieve important goals, both legislatively and professionally.

The Task Force, composed of representatives from all pharmacy organizations in North Carolina, identified six states (Hawaii, Indiana, Iowa, Michigan, Tennessee and Wisconsin) where efforts are underway to consolidate pharmacy into a single state-wide organization. Approaches ranged from creating sections within the existing state pharmaceutical association (e.g. Iowa) to creating an entirely new organization that would create a "fresh start" (e.g. Wisconsin). One representative from Iowa and one from Wisconsin were invited to attend and make presentations at the annual North Carolina Pharmacy Leaders' Forum held Feb. 6-7, 1998. The response was extremely positive and resulted in (unanimous) adoption of a motion to:

"Establish a single organizational structure for pharmacy in North Carolina, and to include in the job description of the new executive director for NCPhA the responsibility to help develop this organization."

The Wisconsin speaker,Curtis Johnson, provided a very detailed listing of goals, methods and resources used to establish the Pharmacists Society of Wisconsin. Two years elapsed from the time of informal discussions to formal implementation of a completely new organization in Wisconsin.

Some of the benefits of uniting pharmacy in North Carolina into a single voice include: (1) to improve our ability to present a unified voice for pharmacy on political, financial and social issues, (2) to consolidate the activities of different pharmacy organizations and decrease the competition for resources, (3) to expand services to pharmacists and encourage collaboration between practitioners from different settings, (4) to promote public awareness of pharmacy's mission to optimize drug therapy, (5) to meet future information and training needs for pharmacy practice, and (6) to strengthen relationships between pharmacy students and practitioners.

The Task Force believes two issues are critical if we are to achieve *One Voice-One Vision for Pharmacy* in North Carolina. Most importantly, the entire effort must be founded on a commitment to improved patient care. An overriding emphasis on improving drug therapy outcomes is critical to finding a common theme around which all pharmacists can unite (and for which there is public support). A second critical issue is the need to identify issues that are held in common versus those issues representing the special interests of individual practitioner groups. The former must form the shared agenda for a single, organizational structure, while the latter must be respected and accommodated within that structure. Finally, the success of a single organization cannot be measured by its membership size, asset mix or range of activities, but rather by the health and vitality of the profession of pharmacy under *One Voice-One Vision.*

It is clear the process for achieving a single structure for pharmacy in North Carolina has many unknowns. We cannot know what approach will work best at this time. However, it is equally clear that the excitement generated by the phrase *One Voice-One Vision for Pharmacy* strikes a strong chord among all pharmacists. We believe the evidence of many states moving toward a single organization representing pharmacy, the enthusiasm of the 1998 Pharmacy Leaders' Forum for this concept and the unique circumstances faced by NCPhA at this time make it imperative that North Carolina pharmacy moves toward *One Voice-One Vision* as quickly as possible.

Conclusion: In summary, the Task Force on Membership recommends that a *One Voice-One Vision* initiative in North Carolina be pursued in the coming year. This effort will require strong commitment from NCPhA members, staff and elected leaders, but has the potential for enormous benefit. We believe two important steps are required: (1) for the membership to embrace a *One Voice-One Vision* initiative by overwhelming majority vote, and (2) for NCPhA to take a leadership role in creating a new organization structure for pharmacy in North Carolina. To expedite these steps the Task Force is distributing a survey of members attending the NCPhA Annual Meeting to elicit their thoughts on this matter and is presenting a motion at the Saturday General Session asking the Association to commit to a process leading to *One Voice-One Vision for Pharmacy.*

Respectfully submitted,

Task Force on Membership Services
Bill Campbell, Chair
Ross Brickley
Frank Burton
Tim Giddens
Ginger Lockamy
Jeff Peterson
Ralph Raasch
Tim White
Deby Wrenn

American Lung Association Launches Asthma Attack

One out of every 18 children in North Carolina may suffer from asthma. The American Lung Association of North Carolina (ALANC) estimates that nearly one-third of all who suffer from acute asthma are unaware of how to manage or prevent potentially dangerous episodes.

To help promote asthma awareness, September 1998 has been designated as "Attack Asthma Month" in North Carolina. The ALANC and its medical section, the North Carolina Thoracic Society have joined Glaxo Wellcome in launching this effort.

With educational support and sound medical intervention, there is good news in the battle to control asthma. Yet the story remains a tragedy in our state. Unfortunately, our state's asthma rate and deaths from asthma have nearly doubled in the last decade. The asthma prevalence rate has increased by almost 60 percent (according to a study published by the American Lung Association).

Pharmacists can play a vital role in education, management and prevention of acute asthma episodes. Many pharmacists across the state have taken an important step toward taking control of this disease by participating in the asthma certification program designed by local area health education centers and cosponsored by the North Carolina Center for Pharmaceutical Care (NCCPC) and the University of North Carolina School of Pharmacy's Continuing Education Program.

One of the coordinators of the program, Peter Gal, PharmD from Greensboro, has already made a difference. He realizes that pharmacists play many roles in the community in addition to being just health care professionals. One of his roles includes being a volunteer soccer coach in a local soccer association.

"Many young athletes enjoy soccer and several of these children have asthma," explained Gal. "Sometimes the only presentation of asthma is with exercise." Some children seem to be trying their hardest, but may appear to be lazy or poorly conditioned because they have to stop chasing the soccer ball or the opposing player, and they appear to give up. This invariably leads to some parents complaining or yelling at their child to make a better effort. In one such case, a young man on Gal's team could not have tried any harder.

"At practices he was always attentive and motivated, and he always seemed to work as hard as he could until he would appear to become breathless and start coughing," said Gal.

Gal asked the boy's mother if her son had ever been worked up for asthma. She said the child's physician did not deem him severe enough to be labeled an asthmatic at the time and no medication was prescribed. With Gal's extensive work in an asthma clinic, he understood the reluctance of the physician to label this child as asthmatic.

Gal's solution was to bring a peak flow meter to the next practice. "After documenting his pre-exercise peak flow values we began practice, and after 10 minutes of scrimmage the child was experiencing the symptoms again," said Gal. "We repeated the peak flow, and the measure had dropped to below 50 percent of his baseline."

The information was passed on to the child's physician with a note from Gal that said the child could no longer play soccer due to his condition until his doctor gave him an inhaled beta agonist to take prior to practices and games. The physician agreed and albuterol prior to exercise was prescribed. "With his exercise capacity markedly increased, this young man became one of the players on the team and was able to excel at a sport he truly loved."

You too can make a difference in an asthmatic's life. Help us "Attack Asthma" and join our efforts to raise public awareness by building coalitions and updating medical care givers in hospitals, schools and the community. If you would like to receive materials, make a suggestion or have a question, ALANC would like to hear from you.

"We need to reach the public by bringing forward human interest stories, patients, care givers and local examples of people who are thriving because they are managing their asthma properly," said Jeff Greene, Director of Special Projects for the ALANC. For more information, contact 1-800-LUNG-USA.

The American Lung Association has been fighting lung disease for over 90 years. With the generous support of the public and the help of our volunteers, we have seen many advances against lung disease. However, our work is not finished. As we look forward to our second century, we will continue to strive to make breathing easier for everyone. Along with our medical section, the American Thoracic Society, we provide programs of education, community service, advocacy and research. The American Lung Association's activities are supported by donations to Christmas Seals and other voluntary contributions.

Community Pharmacy in the New Millennium

Margaret Booth - UNC School of Pharmacy- PY2

"Hello. May I speak to Susan?"

"This is she. May I help you?"

"Yes, this is Mary. I am the technician at Carolina's Drug Store. I just wanted to let you know that the prescription that your physician e-mailed us is ready, and I would like to schedule an appointment for you to come pick it up. As you may not know, since this is your first prescription filled here, you will need to pick a time when you will be able to spend about 15 minutes with one of our PharmDs. They would like to talk to you not only about the drug that your physician has prescribed for you today, but collect medical information so that they will be able to serve you most effectively."

"How about 3:30?"

"That would be perfect. We will see you then. Please do not forget to bring your insurance information."

"Thank you. Bye."

"Bye."

Pharmacy is rapidly changing. Over the last 10 years, we have seen local pharmacies disappear and chains take over. We have seen managed care invade our society through insurance, health maintenance organizations and increasing government involvement in the health care industry. We have seen the role of pharmacists change from a dispenser to a health care provider. We have seen schools changing their programs to teach pharmaceutical care and not just pharmaceutical dispensing. So, it only makes sense that our concept of community pharmacies will no longer apply as we leap into the new millennium.

It is my prediction that the ideas of pharmaceutical care and continuity of care will be the backbone of the future for community pharmacies. Technicians will take over the jobs of filling, order entry and inventory control. Pharmacists will be busy setting up their own "practice" just as the internist whose office is next door. Pharmacists will see patients in rooms, their accessibility will decrease and cognitive services will be employed. There will be a fee for each consultation or office visit. Pharmacists will continue blood pressure monitoring and diabetes education and expand their scope of practice to include prescribing and monitoring of other disease states such as thrombolytic disorders. Insurance companies will laud the effort of pharmacists because they are able to save money by preventing many errors from occurring and save money by eliminating the need for seeing a physician. Customers will, also, laud the enlargement of pharmacist's scope because they have a better understanding of their medication and are having to spend less money because of better results.

Utopia? one may ask. No. This is where community pharmacy will go. The only way we will get there is continued education, unification and persistence. It is exciting to think of the opportunities that await. We should all leap forward with both feet first.

Margaret Booth is the 1998 Ralph P. Rogers Jr. Award winner. This is her award-winning essay.

STUDENT ESSAY

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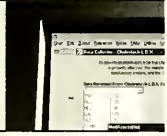

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1998 N.C. Indigent Care Conference

"Tell your story, and tell it often."

With those words, C. Robert Bell, vice president of ministry for the Samaritan's Purse/World Medical Ministry, opened the 1998 North Carolina Indigent Care Conference. Over 130 participants from four states attended the meeting held at the Mountain Area Health Education Center in Asheville, N.C. The conference was hosted by the ABCCM Medical Ministry.

Bell used the story of the Good Samaritan to inspire conference participants to continue their important work. "When you think of the cost for getting treatment and the time it takes for the poor to travel, to have more broad-based clinics in the community is going to be so helpful," said Bell.

Bell likened the mission of Samaritan's Purse in Africa to the work of groups like the new North Carolina Indigent Care Association in trying to ensure health care access for the poor. "In most parts of the world, such as Africa where we do a tremendous amount of work, if it was not for the volunteer mission hospitals, most people would not be able to see a doctor or go to a hospital," said Bell.

The North Carolina Indigent Care Conference, which is in its eighth year, brings staff and volunteers from community-based, volunteer health care programs together once a year to network and learn about ways to establish, maintain and enhance their volunteer efforts to provide health care for all in their communities. The theme for the 1998 conference was community collaboration and partnerships. Workshops dealt with such topics as starting a new clinic, pharmacy solutions, immigrant health, fund raising, volunteer recruiting and communications.

Special luncheon sessions each day dealt with timely subjects for the conference participants. On Wednesday, Calvin Underwood, director of the Buncombe County DDS, discussed welfare reform and its potential impact on free clinics. Thursday's talk featured Tom Lambeth, executive director of the Z. Smith Reynolds Foundation, who discussed the recently passed legislation regarding the possible conversion of BlueCross/Blue Shield.

Several sessions of the conference were designed to allow participants to share information on the growing problems involving pharmacy services. Mark Cruise, executive director of the Virginia Free Clinic Association, put the problem into perspective when he stated, "The three main problems facing every free clinic are pharmacy, pharmacy, pharmacy!"

Glenn Pierce, director of the ABCCM Medical Ministry, noted, "There are really two main problems related to pharmacy services. This first is how to cope with the drastically increasing cost of medications for uninsured and under insured patients. And the second is how to encourage busy community pharmacists to give desperately needed volunteer time in community clinics."

A highlight of this year's conference was the first meeting of the North Carolina Indigent Care Association. The state association has been formed to better coordinate and support the efforts of the free clinics in North Carolina. Dr. Don Lucey, of Raleigh, was elected the first president of the new organization. Other officers and board members elected were Sandy Motley, vice president, Lexington; Jerri White, secretary, High Point; Glenn Pierce, treasurer, Asheville; Carolyn Peck, director, Salisbury; Marilyn McNeely, director, Raleigh; and Dottie Jurek, director, Fayetteville.

The Conference was sponsored by Mountain Area Health Education Center, North Carolina Medical Society, North Carolina Academy of Physician Assistants, Asheville Buncombe Community Christian Ministry and the Mission St. Joseph's Health System.

For more information on the North Carolina Indigent Care Association, contact Glenn Pierce, ABCCM Medical Ministry, 155 Livingston Street, Asheville, NC 28801. (828) 259-5339.

"The three main problems facing every free clinic are pharmacy, pharmacy, pharmacy!"
Mark Cruise,
Executive Director of the Virginia Free Clinic Association

"There are really two main problems related to pharmacy services. The first is how to cope with the drastically increasing cost of medications for uninsured and under insured patients. And the second is how to encourage busy community pharmacists to give desperately needed volunteer time in community clinics."
Glenn Pierce,
Director of the ABCCM Medical Ministry

CONVENTION '98 WAS GREAT!

The President's Perspective

by W. Keith Elmore

After having returned from our annual convention in Chapel Hill, I was impressed by several things:

- The hard work and dedication of our staff toward ensuring that the meeting ran as smoothly as possible.
- The content of the meeting itself. Each session was extremely interesting and informative.
- The support of the exhibitors.
- The enthusiasm, interest and words of encouragement from the individual members present.

In my comments during the closing banquet at the convention, I mentioned that we would have many opportunities to improve our condition. We are also blessed with the means to recognize and take advantage of those opportunities. We have a willing and able staff led by our new executive director, Dan Garrett. We have support of the school of pharmacy at UNC and Campbell. We have good relations with our partners in industry, computer companies, drug wholesalers and others who support our efforts to deliver better patient care. But certainly our greatest asset is who we are: pharmacists — by definition people who care about people, professionals interested in preserving and improving our honored profession and members of an association to meet these ends.

Ralph Waldo Emerson said, "The task ahead of us is never as great as the power behind us." We have tremendous power behind us to accomplish the tasks before us. Let's recognize and use that power constructively and beneficially to improve the state of our patients and our profession.

Remember the Lessons from the Geese:

1. As each goose flaps its wings, it creates an "uplift" for the bird following. By flying in a "V" formation, the whole flock adds 71 percent more flying range than if each bird flew alone.
LESSON: People who share a common direction and sense of community can get where they are going quicker and easier because they are traveling on the thrust of one another.

2. When a goose falls out of formation, it suddenly feels the drag and resistance of trying to fly alone and quickly gets back into formation to take advantage of the lifting power of the birds immediately in front.
LESSON: If we have as much sense as a goose, we will join in formations with those who are headed where we want to go.

3. When the lead goose gets tired, it rotates back into the formation and another goose flies at the point position.
LESSON: It pays to take turns doing the hard tasks and sharing leadership. As with geese, people are interdepedent on each other's skills, capabilities and unique arrangements of gifts, talents or resources.

4. The geese in formation honk from behind to encourage those up front to keep up their speed.
LESSON: We need to make sure our honking from behind is encouraging, not something less helpful.

5. When a goose gets sick or wounded or shot down, two geese drop out of formation and follow their fellow member down to help provide protection. They stay with this member of the flock until he or she is able to fly again or dies. Then they launch out on their own, with another formation or to catch up with their own flock.
LESSON: If we have as much sense as the geese, we'll stand by one another like they do.

Surely we have as much sense as geese.

1998-99 NCPhA President, W. Keith Elmore, sports his President's Jacket provided by Glaxo Wellcome.

Jimmy Jackson and his wife, Peggy, enjoy his last moments as NCPhA president at the President's Reception sponsored by Eckerd.

Awards

Congratulations to the following recipients of awards at the 118th Annual North Carolina Pharmaceutical Convention in Chapel Hill on May 28-30.

- North Carolina Pharmacist of the Year — Jimmy S. Jackson, Garner
- The Don Blanton Award — Fred M. Eckel, Chapel Hill
- The Wyeth-Ayerst Bowl of Hygeia — J. Frank Burton, Greensboro
- The DuPont Pharma Innovative Pharmacy Award — Mary Lynn Bell, Chapel Hill
- The Pharmacists Mutual Companies Distinguished Young Pharmacist Award — Laura McArthur Brewer, Knightdale
- The Campbell School of Pharmacy Preceptor of the Year — Lydia Woodard, Goldsboro
- The UNC School of Pharmacy Practitioner-Instructor of the Year — Tommy Dagenhart, Belmont
- UNC School of Pharmacy Recognition of Merit — Larry Brown, Greensboro
- The McKesson Presidential Award — W. Keith Elmore, Wilmington
- The NCPA Leadership Award — W. Keith Elmore
- The Glaxo Wellcome NCPhA President's Jacket — W. Keith Elmore
- Special presentation of President's Jacket — Fred M. Eckel
- The NCPhA President's Award — Jimmy S. Jackson
- The Bristol-Myers Squibb Presidential Award — Jimmy S. Jackson

Four new members were inducted into the NCPhA 50 Plus Club for 50 years of service in the pharmacy profession.

- Brainard Monroe Burrus, UNC School of Pharmacy 1948, Martin's Drug Store, Canton
- David Dortch Claytor, UNC School of Pharmacy 1948, NCPhA Past President, 1993 Pharmacist of the Year, Greensboro
- Roy Edwin Craft, 1944 Graduate MUSC, Formerly with Smith Drugs, Gastonia
- Ellerbe Wilson Griffin Jr., Former owner of Griffin Drugs, Kings Mountain

New Officers

CHAPEL HILL—NCPhA named four new officers to the Executive Board at the closing banquet. The new initiates were elected by vote of the current membership. Kevin Almond (left), assistant dean at the UNC School of Pharmacy, will serve as president-elect of the organization. Three new members will begin two-year terms on the Executive Board. Jennifer Burch (right), 1993 graduate of Campbell School of Pharmacy, practices at Central Pharmacy in Durham. Gene Minton (not pictured), 1975 graduate of UNC School of Pharmacy, is president and CEO of Drugco Discount Pharmacy in Roanoke Rapids. Benny Ridout (center), resides in Morrisville and is the director of the Medicaid Pharmacy Program for North Carolina. The new initiates will join President W. Keith Elmore and committee members Constance A. McKenzie, Joseph S. Moose and William H. Morris in running the Association.

New board members (from left to right): Kevin Almond, Benny Ridout and Jennifer Burch.

1998

Thanks, Exhibitors!

AmeriSource Corp.
BakerAPS
Barr Laboratories Inc.
Baxa Corp.
Bayer
Bayer Corp. Pharmaceutical Division
Bergen Brunswig Drug Co.
Bindley Western Drug Co.
Brightstone Pharma Inc.
Campbell University School of Pharmacy
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Genzyme Corp.
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Gold Standard Multimedia Inc.
HCC - Liberty Systems
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McKesson Drug
McNeil Consumer Products Co.
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Merz Pharmaceuticals
NC Mutual Wholesale Drug Co.
NCPhA
NC PRN
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Pharmacists Mutual Insurance Co.
PharmaSTAT Inc.
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Searle
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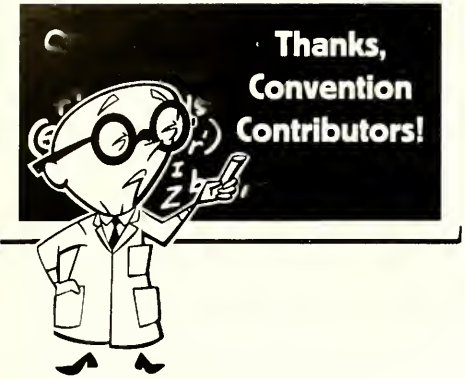
The Financial Group
The Liposome Co.
VIP Computer Systems Inc.

Congratulations to Emil Cekada who won the grand prize drawing at the NCPhA Exhibit Booth.



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Above: The Woman's Auxiliary members were sure to be noticed on the Walk-A-Thon in their "Party til yer Green" shirts.

Left: Fred Eckel was speechless as he received his honorary President's Jacket at the Closing Banquet.

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POTENTIALLY LIFE-THREATENING INTERACTION BETWEEN MIBEFRADIL DIHYDROCHLORIDE AND CERTAIN HMG CoA REDUCTASE INHIBITORS; DRUG PULLED FROM MARKET

Editor's Note: Mibefradil was voluntarily withdrawn from the market on June 8, 1998. This was based on evolving information demonstrating the potential for numerous pharmacokinetic and pharmacodynamic drug interactions with other commonly used medications. This points out the importance of the pharmacist's role in post marketing surveillance of new medications. This article was written prior to the withdrawl.

Christopher J. Sugg, PharmD candidate, and Kristie C. Reeves, PharmD candidate, UNC School of Pharmacy

Mibefradil dihydrochloride, marketed as Posicor®, was approved for use in the United States by the FDA on June 20, 1997 (1). It is touted as the only calcium channel blocker on the market that selectively blocks the transient, low voltage-activated, T-type calcium channels in addition to the long-lasting, high-voltage-activated, L-type channels, whereas other calcium channel blockers on the market act only on the L-type calcium channels (2). To date, this medication has been approved for the treatment of stages I and II essential hypertension, as well as chronic stable angina. Dosing guidelines recommend a daily regimen of 50 to 100 milligrams. Further, the utility of mibefradil dihydrochloride in the milieux of arrhythmia and heart failure are under investigation (3). While this drug has shown substantial efficacy in regards to treating hypertension and angina, several case reports have recently arisen in which a drug-drug interaction between mibefradil and certain HMG- CoA reductase inhibitors (commonly referred to as "statins") was suspected as the culprit in inducing potentially life-threatening rhabdomyolysis.

What is the foundation for this drug-drug interaction? A discussion of mibefradil metabolism in vivo will evoke a satisfactory explanation for pharmacists. First, the active parent compound is extensively metabolized by the liver (97%). While esterase hydrolysis appears to be the major metabolic pathway for mibefradil, another significant pathway involves the cytochrome P450 3A4 (CYP3A4) isoenzyme metabolic system (3). This system is responsible for the metabolic elimination of many drugs. Mibefradil suppresses the activity of CYP3A4, and therefore can interact with concomitant medications, increasing their plasma concentrations. For medications that can cause serious side effects if concentrations are increased, this can be a potentially life threatening interaction.

Coadminstration of Posicor® (mibefradil) with lovastatin or simvastatin should be discouraged due to their extensive metabolism through CYP3A4 (3). In addition, pending availability of further information, coadministration of mibefradil with atorvastin or ceruvastatin should be generally avoided because both atorvastatin and ceruvastatin are biotransformed by CYP3A4 to active and inactive metabolites (3). Furthermore in a clinical study were atorvastin and ceruvastatin were combined with erythromycin (a less potent inhibitor of CYP3A4) small changes in HMG-CoA reductase inhibitor activity were observed.

Not all statin cholesterol reducing agents are identically metabolized. Fluvastatin and pravastatin are metabolized by processes that are independent of the CYP3A4 isoenzyme. Posicor® (mibefradil) coadministered with either of these medications would not be expected to increase the incidence of rhabdomyolysis associated with fluvastatin and pravastatin.

Roche has received documented domestic reports of statin-induced rhabdomyolysis in patients receiving lovastatin or simvastatin (1). Since both agents are dependent of the CYP3A4 for their metabolism, it is believed that in normal volunteers an elevation of twentyfold or greater can occur while on statin therapy. For this reason, the labeling of Posicor® (mibefradil) has been revised to state that coadministration of Posicor® (mibefradil) and lovastatin or simvastatin is contraindicated.

Rhabdomyolysis is caused by a number of medical circumstances such as diabetic crises and Legionnaire's disease. This condition evolves primarily from skeletal muscle disintegration. While drug induced muscle injury is a rare side effect of all HMG-CoA reductase inhibitors, it seems to increase in frequency with increasing dose or coadministration of medications metabolized by the same route. Patients with drug induced muscle injury usually experience nonspecific muscular symptoms (weakness, tenderness and pain), but the most important consequence of this interaction is not muscular. The breakdown products of muscle can cause temporary or permanent damage to the kidneys, and in severe cases, the heart can also be affected. Either complication can lead to death. The use of Posicor® (mibefradil) as monotherapy does not cause muscle injury, but the incidence of rhabdomyolysis appears to be much higher when either simvastatin or lovastatin is coadministered with mibefradil.

What is the significance of this interaction to pharmaceutical care providers? The answer is quite clear. Many patients who are afflicted with angina or hypertension have co-existing hyperlipidemic conditions. Since prescribing trends regarding antianginal, antihypertensive, and antihyperlipidemic therapies are largely physician-specific, it is imperative for pharmacists to be aware of this potential interaction between mibefradil and lovastatin or simvastatin. Furthermore, although no drug-drug interaction between mibefradil and atorvastatin or ceruvastatin has been documented to date, caution should be exercised as well.

Health care providers should report any adverse events related to Posicor® (mibefradil) to Roche Laboratories (800-526-6367) or to the FDA. Reports may be submitted to the FDA by telephone (800-332-1088), by fax (800-332-0178), or by mail 5600 Fishers Lane Rockville, MD 20857.

References

1.] http://pharminfo.com/medwatch/mw1pt31.html

2.] Bakx A, van der Waal E, Braun S et al. Effects of the new calcium antagonist mibefradil on exercise duration in patients with chronic stable angina pectoris. a multicenter, placebo-controlled study. AHJ 1995; 130:748-57.

3.] Product Information, Posicor® 1997.

4.] Product Information, Lipitor® atorvastatin 1997

"If you build it, they will come."

From the movie Field of Dreams

NCPRN HELPLINE
336-774-6555

The first quarter of 1998 was one of tremendous growth for NCPRN. On Dec. 1, 1997, we moved into our new office, and from Jan. 1, 1998, until now, NCPRN has taken on a total of 16 new cases. In eight of those instances, the person had his/her pharmacy license. So far, all of the cases in 1998 have been males, which is unusual when you consider the ever increasing number of women in our profession.

However, these numbers are quite significant when you consider we only had a total of five new cases in 1995 and 1996, and 16 cases in all of 1997. If we continue at this pace, we will have taken on over 60 new cases in 1998, with a total caseload of almost 100 by the end of this year. Probably the most significant statistic is that we have been able to help four independent store owners not only recover from the disease of addiction, but also keep their stores open.

Our 3rd annual CE Program in Asheville had 42 attendees made up of mostly pharmacists and a few substance abuse counselors. Attendance was somewhat less than expected, but was likely due to a combination of location and the NCAA basketball tournament. As has been the case with previous CE programs we have sponsored, many noted on the evaluations that it was the best CE they had ever attended! Our next program will be held on Nov. 15, 1998, in Raleigh and will focus on the special issues of women pharmacists in recovery. Look for brochures in the mail in October.

Throughout 1998 our relationship with the Board of Pharmacy has continued to get stronger. We are about to enter into a Memorandum of Understanding with the Board which will further enhance and strengthen our relationship. This arrangement will allow for pharmacists to enter into a deferred prosecution agreement with the Board and NCPRN, as well as keep their name out of the Board's newsletter.

Overall, this past quarter and past year has been one of great success for NCPRN. I am optimistic that this sense of prosperity and growth will continue into the future.

NCPRN Statistics Through May 1998

Male		36	85 percent
Female		6	14 percent
Current Rx License		30	71 percent
Average Age		41	
Number of new cases per year	1995	5	
	1996	5	
	1997	16	
	1st quarter 1998	16	
Under Board of Pharmacy Order		18	42 percent
Relapse		5	12 percent
Relapse with current recovery		4	80 percent of relapses
Area of Practice			
Chain Retail		28	66 Percent
Independent		4	10 percent
Hospital		4	10 percent
Other (LTC, Industry)		5	12 percent
Student		1	2 percent

NORTH CAROLINA SOCIETY OF HEALTH-SYSTEM PHARMACISTS NCSHP Newsletter

Volume 21, Number 3 The bimonthly publication of the North Carolina Society of Health-System Pharmacists July/August 1998

PressScription for Success upcoming focus

I just returned from the ASHP Annual Meeting in Baltimore and was excited to learn the specifics of ASHP's new public relations campaign. ASHP will be marketing the profession of pharmacy in a coordinated campaign that promotes pharmacy nationally, as well as concurrently providing public relations resources at the state society grass roots level. Copies of "PressScription for Success," a how-to kit to help plan, promote and implement grassroots public relations activities to increase the visibility of health systems pharmacists, were provided. NCSHP's Communications/Public Relations Committee will be providing details soon on establishing a plan for pharmacy in North Carolina.

The need to increase pharmacist visibility is critical if we want to continue to have a say in our professional future. Our lack of visibility and the public's failure in understanding our role in health care undermine our professional growth. This lack of visibility was demonstrated recently by several consumer surveys conducted by a public relations firm for ASHP. Health care consumers, when asked to list their hospital caregivers, routinely omitted pharmacists. Only when pressed about the source of their medications in hospitals, did they make the connection with pharmacy, and then, pharmacy was listed secondary to nursing! As a profession, we have to make a concerted effort to get out of the pharmacy and provide direct care for, and value to, the patient. Consistently providing that care is not enough, however. We have to take every opportunity to market ourselves and our profession to the patient and the public. Here are some ways to get started:

Patient contact

• Make sure the services of pharmacists are included in your health system's written orientation materials for the patient.
• When you have contact with a patient, make sure the patient knows you are a pharmacist.
• Make a point to talk to patients about their medications. Give patients your business cards and invite follow-up calls, if possible.
• If you counsel patients at discharge, briefly point out how pharmacists contribute to their care during their hospital stay. Also, offer to call the patient's community pharmacist if the patient is concerned about any matter that will be handled by that practitioner.
• When you confer with other professionals to improve the treatment of an ambulatory patient, tell the patient what you have done and why.

Community Outreach

• Meet with your health-system's public relations director about including pharmacists in future activities, such as health fairs, community newsletters, prevention and wellness programs.
• Offer your services for a "brown bag" program.
• Respond to issues in the news with a letter to the editor.
• If your health-system has a Web site, offer to create and maintain a section such as "Medication Tips from the Pharmacist," where consumers can access recommendations for safe medication use.

Marketing our services and contributions to patient care essential in sensitizing patients, payers and regulators to our value as a profession. Marketing ourselves is essential in providing a positive pharmacy environment in such areas as HCFA regulations, Board of Pharmacy rules, practice act legislation, insurance reimbursement and managed care contracts. By educating the patient and public on the role of the pharmacist and the value of pharmacy, we are taking a proactive role in determining our future.

Submitted by Steve Novak, MPA, Director of Pharmacy, Gaston Memorial Hospital, Gastonia and 1998-99 NCSHP President.

Managed Care/Managed Cost Topic for Fall Mtg

The NCSHP Program Committee in conjunction with the UNC Continuing Education Department has put together a fall meeting that promises to deliver up-to-the-minute information for pharmacists across the state. The first day's programming includes new drugs used to treat diabetes and managing cardiovascular disease in patients with diabetes for the morning session.

The afternoon session will focus on the difference between managed care and managed cost in the current health delivery environment. There will also be a discussion of pharmaceutical care services that add value to a stand-alone hospital's or IHS' customers.

The second day's programming includes anticoagulant therapy in the morning and a pharmacotherapy update on quinolones and treatment of HIV. As usual, the Exhibit Program will be held both days and the Residency Showcase is scheduled for the first day of the meeting. Brochures will be mailed in August to NCSHP members.

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NCSHP Newsletter is a bimonthly publication of the North Carolina Society of Health-System Pharmacists (NCSHP), a non-profit organization dedicated to the enhancement of health-systems pharmacy practice. Subscription to the newsletter is a benefit of membership in NCSHP.

NCSHP members are encouraged to share their views, concerns and ideas with their colleagues by contributing articles to The ***NCSHP Newsletter***. Opinions expressed are those of the authors and may not represent the views of NCSHP, its officers, Board of Directors or its membership. Copy deadlines are the 15th of the odd month for the Newsletter to be published the next odd month.

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Choose your predecessors carefully

The notion of choosing your predecessor conjures up thoughts that seem at odds. That is, how does one choose their predecessor? Can one really choose a predecessor? If so, can they do it carefully? I have had the good fortune to have great predecessors, but I cannot take credit for choosing them consciously or doing it carefully.

Early in my career I was told that the first years of profession practice are important for developing one's own practice style. This idea helps remind us about the importance of actively planning a career versus meandering down the career road to anywhere. It is easier advice to give than to live. More recently the concept of life-long learning was touted as a requirement to maintain contemporary skills and develop new abilities to meet the challenges and opportunities of tomorrow.

Surrounding oneself with great people is one of the foundations of success.

Is it true that the best person doesn't always get the job but rather the person who talks the best? I hope not. The best career opportunities are in the eye of the beholder, very individualized and personal. Surrounding oneself with great people is one of the foundations of success and the power of involvement of more people in decisions seems to raise the results exponentially.

Regardless of where we work, the place and its name are only the bricks and mortar. The heart of that workplace is its people, their sense of purpose and accomplishment through achievement of their individual and organizational goals, one patient at a time. Whenever possible to implement, shared governance stimulates ownership of decisions and successes to energize everyone involved.

Pharmacy practice today requires great personal and professional energy. Profession growth requires that we reinvest in our future and the future of our colleagues using all available tools and technology. Harnessing data streams for transformation into information to be placed in the hands of pharmacists for improving patient care is the cornerstone for the future of pharmacy.

We must constantly seek new ways to assure the best use of medicines for our patients and not be threatened by failure or uncertainty. Those willing to take risks, stretch their practice and collaborate with other health care practitioners are the profession's future successes.

The dilemma is only to continue accepting the challenge and putting plans into action. Time is wasting. Good luck Mr. Phelps.

Submitted by Stephen C. Dedrick, M.S., Director of Pharmacy, Duke University Hospital, Durham.

Call for nominations-deadline Sept. 15, 1998

The Nominations and Awards Committee issues this call for candidates for Pharmacist-of-the-Year and the NCSHP offices. The Committee will announce the Pharmacist-of-the-Year and present the officers' slate at the NCSHP Fall Meeting. Nominations are needed for the following:

PHARMACIST-OF-THE-YEAR,
PRESIDENT-ELECT, BOARD OF DIRECTORS (2),
EXECUTIVE SECRETARY, ASHP HOUSE DELEGATES (4)

To obtain award criteria or for a job/position description, please contact the NCSHP office or Chair Tim Giddens. Suggestions and nominations should also be sent to Chair-Tim Giddens, MS, Director of Pharmacy, Southeastern Regional Medical Center, 300 West 27th St., Lumberton, NC 28358 (910) 671-5176.

NCSHP 1998 ANNUAL REPORT

President Giddens highlights 1997-98 year

1997 may well be remembered as a crossroads for the North Carolina Society of Health-System Pharmacists (NCSHP). It was a very busy year, filled with action and controversy. Controversy concerning the Board of Pharmacy's Institutional Rules, controversy in change in executive leadership in both NCSHP and NCPhA, controversy around the Pharmacy Practice Act revision, controversy over our relationship with other professional pharmacist associations and controversy over Board of Pharmacy composition. But I am very certain that out of this year of controversy NCSHP will move on, strengthened, renewed and committed to its mission of supporting its members in delivering pharmaceutical care.

I would like to thank all of the officers, committee and SIG chairs and committee members who made this year a productive one. The committee structure is the way the Society gets things done, and as President, I appreciate the hard work which was given this year.

I. Committee Highlights

The NCSHP Mentorship Program was developed by the Membership Committee to provide new Society members an introduction to the Society, its programs and committee function. New members are the future leaders of the Society and the profession, and this investment is well worth your time and efforts. The Pharmacotherapy SIG developed a review series for the Board of Pharmaceutical Specialty Pharmacotherapy exam.

The Communication and Public Relations Committee, under an ASHP affiliated-chapter grant, developed a billboard campaign promoting the role of pharmacists in safe medication use, with 15 billboards across the state. The Legal and Regulatory Committee helped implement the Board of Pharmacy Institutional Rules, developed Society positions on new rules on technician ratios, compounding and Board of Pharmacy composition, and assisted the Society Board on Practice Act revision considerations.

II. Pharmacy Practice Act

The Pharmacy Practice Act revision was introduced in the 1997 Long Session of the Legislature. The heart of the change is the inclusion of providing pharmaceutical care as part of the "practice of pharmacy" and the authorization of a pharmacist to manage drug therapy under a collaborative agreement with a physician. As expected, there were concerns both from the pharmaceutical manufacturers and the North Carolina Medical Society. The Bill was sent to the Health Care Oversight Committee for consideration in the 1998 Short Session. Our lobbying efforts in conjunction with NCPhA have made it likely that the Practice Act revision, including collaborative drug therapy management, will be approved this year. The hard work of the Legal and Regulatory Committee, the Society Board and NCPhA have made this possible.

One issue which has been of primary interest to the Society is Board of Pharmacy composition. The Society believes that the current geographical election process does not serve the public interest since it does not insure practice site diversity on the Board of Pharmacy. The Practice Act Revision Committee addressed this issue in some detail and recommended that this be resolved through rule changes rather than the Practice Act. The Society proposed a rule change which would define four Board members elected by geographical representation, and one member who worked in a health care facility. Unfortunately, the Board of Pharmacy defeated this proposal.

As a result of the Board of Pharmacy's action, the Executive Committee of NCSHP granted approval to pursue a Board of Pharmacy composition change in the Pharmacy Practice Act revision, with a proposal to define Board membership by practice site composition rather than geography. We are very optimistic that this change will be included in the Practice Act which is sent to the 1998 Legislature from the Health Care Oversight Committee.

III. Pharmacy Organization Relationships

Increased legislative agendas, a declining volunteer base, expanding educational needs and the need to consolidate and share administrative costs have moved state pharmacy associations nationwide towards developing closer working relationships. This is true in North Carolina, and has been punctuated by the loss of Al Mebane at NCPhA and Frances Gualtieri at NCSHP.

The Society Board has formally discussed the opportunities for NCSHP and voted with the other state pharmacist associations to move forward with a single pharmacy organizational structure which would represent North Carolina pharmacists. The model of such organization is not yet determined, but the Board of the Society is committed to maintaining a structure which would enable ASHP affiliation and serve the unique needs of health-system pharmacists. This process will be a 18-month to two-year effort. 1998-99 President Steve Novak is taking a proactive role in managing this process, which will begin by a joint meeting of the Boards from NCSHP and NCPhA this spring.

Let me thank you again for your help in 1997 and the opportunity to serve you as NCSHP President. No, it was not easy. No, we did not accomplish all of my hopes. No, I would not do it again. But, it was exciting, personally educational, and rewarding. Each of us has a debt to repay to our profession. I encourage you to consider how you can serve pharmacy and NCSHP.

Submitted by Tim Giddens, M.S., 1997-98 NCSHP President and Director of Pharmacy, Southeastern Regional Medical Center, Lumberton.

IN RECOGNITION

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Planning Committee: Steve Novak
Program Committee: Tracy Bane

1997-98 Newsletter Contributors

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Treasurer's Report for 1997

The Society finished 1997 with a net operating income of $-17,678.66 after incurring $138,843.92 in operating expenses. As of December 31, 1997, there was approximately $157,390.13 in assets and liabilities, in contrast to $197.812.52 at the end of FY 1996. Assets, in the form of cash, CD's and account's receivable total about $112,000, with the balance in furnishings and other assets.

Revenue from dues collections were increased over 1996; however, total 1997 collections were $2,800 less than budgeted. Most notably, exhibit expenses increased by $10,000 over budget and newsletter costs were $2,000 more than budgeted.

The Board discussed several trends that have negative financial impact on the Society: (1) total active memberships are decreasing; (2) volunteering is decreasing and more paid staff hours and office expenses/supplies are required to sustain the demand for NCSHP support staff services; (3) meeting expenses continue to increase significantly with the current hotel contract at it most expensive level ever; (4) travel expenses associated with NCSHP business and Board of Director expenses are higher than budgeted; (5) support of the work on the revisions of the Pharmacy Practice Act were the most the Society has ever put into this type of activity; (6) public relations activity continue to increase and cost more with the matching dollars NCSHP supplied for the ASHP Grant for the Billboard Campaign.

For 1998, the Board accepted a report suggesting that operating income needs to increase by approximately $7,000 and expenses should be trimmed to allow for a net operating transfer of $5,900 to the reserve account.

Submitted by John M. Kessler, PharmD, Assistant Director of Pharmacy Duke University Medical Center, Durham and NCSHP Treasurer.

Balance Sheet

December 31, 1997

ASSETS		
Current Assets		
Checking/Savings		
Centura Op Acct	3,181.84	
Centura Mon Mkt	107,582.30	
Total Checking/Savings	110,764.14	
Accounts Receivable		
Acts Receivable	1,290.00	
Total Accounts Receivable	1,290.00	
Total Current Assets	112,054.14	
Fixed Assets		
Furniture & Equipment	6,032.62	
Total Fixed Assets	6,032.62	
Other Assets		
Prepaid Rent	8,612.90	
Wachovia CD #2	30,690.47	
Total Other Assets	39,303.37	
TOTAL ASSETS	***157,390.13***	
LIABILITIES & EQUITY		
Liabilities		
Current Liabilities		
Accounts Payable	6,663.89	
Total Accounts Payable	6,663.89	
Other Current Liabilities		
Prepaid Exhibit	4,550.00	
Prepaid Dues	23,985.00	
Total Other Current Liabilities	28,535.00	
Total Current Liabilities	35,198.89	
Total Liabilities	35,198.89	
Equity		
Opening Bal Equity	58,314.89	
Retained Earnings	81,555.01	
Net Income	-17,678.66	
Total Equity	122,191.24	
TOTAL LIABILITIES & EQUITY	***157,390.13***	

Profit and Loss Statement

January 1, 1997-December 31, 1997

INCOME	
Dues - Current	42,150.00
Exhibit Pgm	39,700.00
Education	24,870.00
Tech. Exam Rebate	3,592.50
Career Line	4,665.00
Org. Aff.	982.50
Investment Income	4,775.32
Contrib. & Gifts	15.00
Video Library	70.00
Lapel Pins	50.00
Other Income	294.94
TOTAL INCOME	121,165.26
EXPENSE	
Exhibit Pgm	23,034.77
Education	7,983.43
Newsletter	13,934.24
Org. Aff.	7,362.91
B. of Directors	6,171.52
Career Line	1,569.24
Committee & SIG	7,903.65
Membership	3,578.78
NCCPC	3,000.00
Pub.& Prof.	5,000.00
Awards	866.60
BCPS Review Course	450.00
Support, staff	34,111.19
Payroll Tax	3,502.95
Support, General	12,340.81
Telephone	1,596.91
Travel	791.67
Rent	1,230.42
Depreciation	1,804.48
Repair & Maint.	308.31
Legal & Professional	1,800.00
Interest Expense	2.04
Contributions	500.00
TOTAL EXPENSE	138,843.92
NET INCOME	***-17,678.66***

IN RECOGNITION

1997-98 Corporate Program Sponsors

Continuing Education Programs

Bayer Pharmaceuticals
Glaxo Wellcome
Purdue Frederick Co.
Wyeth-Ayerst Laboratories

1997-98 Continuing Education Program Exhibitors

Bold face denotes participation in two meetings this year.

Abbott Laboratories
American Red Cross
AmeriSource Corporation
Amgen, Inc.
Apothecon Pharmaceuticals
ARTROMICK
ASHP
Astra Merck
Automated Healthcare, Inc.
Barr Laboratories, Inc.
Baxter Healthcare
Baxter/Clintec Nutrition
Baxter Healthcare Corp., Hyland/Immuno.
Bayer-Pharmaceutical Division
Bedford Labs.-Div. of Ben Venue Labs.
Bergen Brunswig Drug Company
Bindley Western Drug/Carolina Division
Blood Diagnostices, Inc.
Boehringer Mannheim Therapeutics
Cardinal Health, Inc.
Centeon
Dey Laboratories
Diebold MedSelect
DuPont Pharma
Eli Lilly and Company
ESI-Lederle
EXP Pharmaceutical Waste Mgt, Inc.
Glaxo Wellcome
Hoechst Marion Roussel, Inc.
Jones Medical Industries, Inc.
Kol Bio Medical Instruments, Inc.
Lexi-Comp. Inc.
LifeServ Technologies
Marsam Pharmaceuticals, Inc.
McGaw, Inc.
McKesson Automated Healthcare
Medeva Pharmaceuticals
Merch & Co.
Merck Human Health "Acute Care"
Micromedex, Inc.
Novartis Pharmaceuticals
Ortho-McNeil Pharmaceuticals
Paragon Scientific Corporation
Pyxis Corporation
Parke-Davis
Rhone-Poulenc Rorer Pharmaceuticals, Inc.
Roche Laboratories
Roxane Laboratories, Inc.
Searle
Shared Services Healthcare, Inc.
SmithKline Beecham
TAP Pharmaceuticals
The Purdue Frederick Company
The Liposome Company
Translogic Corporation
Wyeth-Ayerst Laboratories
Zeneca Pharmaceuticals

STUDENT/TECHNICIAN' S CORNER

UNC-CH Student Initiative

On April 21, 1998, the pharmacy students of UNC voted to dissolve both the SSHP and ASP chapters for the purpose of creating a unified organization. A driving committee of 10 students was assembled in order to address concerns raised by the student body. Surveys generated and distributed to students indicated that many aspects of the pharmacy profession were not adequately represented by the current organizations. Following the model set by Wisconsin, the Carolina Association of Pharmacy Students (CAPS) was founded.

The mission of CAPS is to be an advocate for pharmacy students by providing resources to develop a professional attitude, enhance leadership skills and promote responsibility for the profession, thereby preparing students for the challenge of optimizing pharmacist care in a dynamic health care environment. Specifically, CAPS will strive to improve communication within the school, increase exposure to career opportunities, and provide more efficient scheduling for meetings, while still maintaining affiliation with both state and national professional pharmacy organizations. The Board of Trustees and faculty advisors of CAPS have already been assembled, and new membership will begin in the Fall of 1998.

Please direct any comments or suggestions to the CAPS Driving Committee at: rkdell@mindspring.com, as we will be working hard this summer for a successful kickoff in August! Members of the CAPS Driving Committee include: Sandeep Singh, Ariel Mihic, Mary Williams, Jill Garris, Kami Dell, Ami Teague Deaton, Macary Weck, Amy Hatfield, Kristin Britton, and Andrea Wessell.

PTCB launches interactive WEB site

The Pharmacy Technician Certification Board (PTCB) has launched its new interactive site on the World Wide Web. The site, located at *http:\\www.ptcb.org*, is another big step in the continued growth of PTCB and its commitment to assist the pharmacist in the provision of pharmaceutical care. Baxter Healthcare Corporation sponsored the development of the Web site.

"The new Web site will provide easy access to up-to-date information for Internet users as well as the means for disseminating the message of the importance of pharmacy technician certification," says Melissa Murer, PTCB Executive Director. "This will allow users to obtain information on time-sensitive issues such as exam dates, application deadlines and test locations at their convenience."

The information provided on the web covers a wide variety of topics and includes:

•PTCB News-Late breaking news directly from headquarters and updates on the formation of new partnerships.

•Exam Information-Specific instructions for the day of the exam as well as suggestions for preparation and sample test questions.

•About PTCB-The PTCB mission statement, executive's report, future activities and state involvement.

•Recertification-Guidelines for recertification as well as for continuing education information and answers to frequently asked questions (FAQ) regarding the process.

The PTCB Web site will also serve as a means of education and informing various interest groups. Consumers, pharmacists and potential employers all now have access to information about PTCB including the history of the organization, statistics and reports, the background and value of certification, state organizations and governing boards.

Links to affiliated organizations are also currently available. One of the features now available on the Web site is an interactive bulletin board which offers the opportunity for Certified Pharmacy Technicians and pharmacists to questions and comments.

Calendar of Events

July 18, 1998
Technician Certification Exam
Asheville, Charlotte, Durham, Fayetteville

August 22-24, 1998
ASHP Home Care Meeting
Chicago, IL

October 7-8, 1998
NCSHP Annual Carolina Seminar
Greensboro

November 14, 1998
Technician Certification Exam
Asheville, Charlotte, Durham, Fayetteville

December 6-10, 1998
ASHP Midyear Clinical Meeting
Las Vegas, NV

February 11-12, 1999
NCSHP Winter Meeting
Greensboro

June 6-10, 1999
ASHP Annual Meeting '99
Reno, NV

July 31-August 2, 1999
ASHP Home Care Meeting
Chicago, IL

October 6-7, 1999
NCSHP Annual Carolina Seminar
Greensboro

1998 TECHNICIAN FALL MEETING AGENDA SET

The Pharmacy Technician Committee in conjunction with the NCSHP Program Committee has set the topic agenda for the 1998 Pharm Tech Fall Meeting Agenda as: (1) Pharmacy Law; (2) TPN-total parenteral nutrition; and (3) herbal medicine. Brochures will be mailed to NCSHP Pharm Tech members, NCSHP hospital and upon request beginning in late August. Contact the NCSHP office at (919) 933-6760 if you wish to be added the NCSHP's mailing list.

NCSHP

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N. C. Society of Health-System Pharmacists
P.O. Box 968
Chapel Hill, NC 27514-0968

Call CAREER LINE at 1-919-967-8980

PRN
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1-910-774-6555

FAX 1-910-774-9010

You may leave your name / number and your call will be returned promptly.

IN SUMMARY

ASHP advocates requiring hospitals to establish failsafe medication use systems

ASHP has organized a multidisciplinary response to a Health Care Financing Administration (HCFA) proposal that would require hospitals to hold their overall medication error rate to no more than 2% in order to be eligible for reimbursement under Medicare and Medicaid. The response, a joint letter, recommends that the agency instead require US hospitals to make it their goal to eliminate medication errors entirely and establish programs to that end, has been signed by ASHP Exec. VP and CEO Henri R. Manasse, Jr., PhD, ScD and three nationally recognized leaders in the field of adverse drug events and quality improvement. Five prominent health care and consumer organizations have endorsed the response.

Lucian Leape, MD, Assoc. Dean of the Harvard Univ. School of Public Health; Donald M. Berwick, MD, President and CEO of the Institute for Healthcare Improvement and Michael R. Cohen, MS, President of the Institute for Safe Medication Practices, joined ASHP in encouraging HCFA to adopt regulations leading to the elimination of medication errors rather than instituting the proposed 2 percent threshold. Organizations endorsing the letter include the American Academy of Pediatrics, American Medical Association, Association of Operating Room Nurses, National Consumers League and Federation of American Health Systems.

The letter argues that the agency's proposed methodology for reaching the goal of reducing medication errors will fall short of the mark, since it is likely to heighten fear among health care workers reporting medication errors and create the impression that the federal government sanctions a certain percentage of mistakes.

The alternate approach advocated is to require each hospital to establish and conduct an active, interdisciplinary, quality-improvement program focused on medication error prevention and elimination. The letter points out that the initiation of active internal monitoring of serious quality problems in hospital care typically leads to an initial finding of more problems than expected. Appropriate follow-up actions then lead to sustainable improvements over time.

Contact Renée Brehio, Director of Public Information Division, ASHP, 7272 Wisonsin Ave. Bethesda, MD 20814, 301•657-3000 for more information on this topic.

The minimum requirements of an effective medication-error prevention program:
(as described in the letter to HCFA)

- ***A standard definition of medication error***
- ***An ongoing process for measuring medication errors and following up on their root cause and instituting safety measures to eliminate repeat incidents.***
- ***A periodic, regular, interdisciplinary institution-wide analysis of medication-use safety, coupled with education and training of relevant staff.***
- ***Identification of the inherently most hazardous aspects of medication use in the institution and systematic efforts to reduce those hazards.***
- ***Reporting of serious medication errors to existing, voluntary national reporting programs in order to foster analyses of root causes of errors and dissemination of information on how to prevent such errors from occurring.***

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Ron Davis, Buford Road Pharmacy, Richmond, VA

"The GNP+ program has helped me return to my profit levels of a few years ago. I can economically do much more and act like a chain, but I still run my store to fit my local market."
Gary Dreyfus, Moulton Plaza Pharmacy, Laguna Hills, CA

"The advertising for Good Neighbor Pharmacy has really had an impact. Bergen Brunswig has put forth the maximum effort to help us succeed. When the Good Neighbor Pharmacy Across America promotional bus came to town, it really reinforced that we are part of a powerful group."
Tom Neale, Pharmacy Plus, Teague, TX

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Robert Sopocy, Family Drug Mart, Port St. John, FL

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GOOD NEIGHBOR PHARMACY

History on Display

by Peter Kanipe

Inside the North Carolina Museum of History lies a new exhibit displaying the roots of professional pharmacy. On April 24, a drugstore display opened as part of the new "Health and Healing Experiences in North Carolina" exhibit. The display, a depiction of a pharmacy in the 1920s, now provides an opportunity for all visitors in the museum to learn how the profession was practiced and what drugstores looked like during the earlier years of the twentieth century.

Visitors to the museum can walk into a drugstore with fully stocked shelves, a pharmacy and soda fountain. All artifacts and pieces in the display are authentic and were given by a number of retired pharmacists and their families who wanted the profession to be understood. Most of the donors worked in small town or neighborhood drugstores which prove to be drastically different from the supermarket and chain pharmacies of present day. These people wanted to point out what pharmacy used to be like and that desire led to an idea.

In 1986, a group of pharmacists met and talked about getting a drugstore into the Museum of History. At that time, the museum had not yet been built. Vivia Creech of Smithfield saw the situation as a great opportunity to share with fellow colleagues. "I just said, 'OK, you pharmacists, the blueprints for the museum are on the board, and if you ever want a drugstore in there, you have to act. It's now or never.'" So on a Sunday afternoon, she and her husband Jimmy conducted a small meeting at their home. Herman and Ernestine Lynch and Barney Paul and Annie Louise Woodard came to the meeting and agreed that a drugstore would be a grand idea.

Herman Lynch called Keith Fearing, president of the North Carolina Pharmaceutical Association. The Association appointed a standing committee of about 30 retired pharmacists and their wives to work with the museum. The committee collected money and antique items from pharmacists around the state. At first, items were hard to find, and the pharmacists worried that the exhibit may not get completed. But they did not stop. "We just kept going; we just kept at it," said Jimmy Creech. "That's the only way we knew it would get done."

Their perseverance eventually paid off. Mary Geyer, owner of a drugstore built in 1904, donated anything that could be used from her store to the museum. Thousands of items from Elsie Booker (see side story), John Brantley of Brantley Drugs and others also came in. Banks Kerr, owner of Kerr Drugs, stored these items in his garage until they could be moved to the museum.

After 11 years, dreams were finally realized at a special preview party for the exhibit in April. Unfortunately, not everyone lived long enough to see the exhibit's opening. Keith Fearing, one of the original four who began work on the exhibit, died 2 1/2 years ago. His wife, Lib, continued his work in building funds for the project. "He would be very happy and very proud to see this," she said. "I think they did a beautiful job."

The North Carolina Museum of History is located on 5 East Edenton Street in Raleigh. It is open from 9:00 a.m. to 5:00 p.m. Tuesday through Saturday and from noon to 5:00 p.m. on Sunday. For more information, contact the museum at (919) 715-0200.

Collector helps exhibit with donations

One of the major heroines in making the drugstore exhibit happen in the Museum of History was Elsie Booker, North Carolina's first female pharmacist. If not for her generous contributions and love of pharmacy, the exhibit quite possibly would never have come together.

Booker started collecting antique pharmaceutical items about 40 years ago. In 1973, she opened a display of her collection to the public at the Patterson Mill Country Store located on Farrington Road in Chapel Hill.

When the search began for antiques to put in the exhibit, only a few items could be found. By 1993, many feared that it was time to give up. But that was when the Museum of History came to Booker and asked for a major portion of her collection.

In 1995, Booker temporarily shut down the pharmacy section in the Patterson Mill store to help with the cause. "I closed the pharmacy for six weeks, pulled the oldest items and gave them to the state," said Booker. She even verified that the items were authentic for a 1920s drugstore by researching medical catalogs at the University of North Carolina at Chapel Hill.

After giving $40,000 worth of items including tins, apothecary jars, ointments, crude drugs, chemicals and hundreds of over-the-counter drugs, Booker's own display was greatly diminished. She then had to revamp her pharmacy collection in order to open it to the public again.

Booker said she was very happy to see the exhibit finally open. "The motive was to share with the people of North Carolina what I had collected in 40 years of collecting. I did it for the love of pharmacy."

New Membership Benefits

The North Carolina Pharmaceutical Association is proud to announce an expansion of its membership benefits program. In addition to the many privileges NCPhA members already receive, our staff has developed a package that includes products and services that your entire family can enjoy. We will continue to look for opportunities to provide additional benefits for our members.

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- Loan and scholarship program for pharmacy students decreasing financial barriers to entering the profession
- A 100-seat auditorium and other facilities available for pharmacy-oriented meetings at the Institute of Pharmacy

Other Products and Services for Members

- Discount on new AAA Membership
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- Discount on *Pharmacist Letter*
- Discount on car rentals
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Health Insurance

- Pharmacists Mutual health insurance options are available. (Call Ron Stoll with Pharmacists Mutual at 1-800-247-5930, ext. 137 to learn about insurance products available to association members.)

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Informal Consultation on Control and Safe Trade in Starting Materials for Pharmaceutical Products May 25-27, 1998 Geneva, Switzerland

by David Work

In the last decade not less than four incidents of poisoning have occurred from the sweet industrial solvent Diethylene Glycol as a contaminant in Glycerin.[1] The actual number is certainly higher but we will never know the full extent of damage done by this misplaced chemical.

A chronological history of toxic results from Diethylene Glycol begins in 1937 in the United States with other deaths in Africa, South America, Asia and most recently in Haiti.[2] It is noteworthy that over 30 years elapsed between the first and second reported episode but recently the average is one tragedy every two years.[3] If anything this indicates a more alert public health reporting system rather than diminished scruples among dealers in pharmaceuticals. Reported cases all involve pharmaceuticals, however, Glycerin is also used in some food products with the same potential for contamination.

Causation for these defective products can be traced to several processes or their absence. In some cases contaminated starting materials have been used which are a by-product of manufacturing of Glycerin by fermentation with sugar. Other incidents resulted from confusion of Diethylene Glycol with Propylene Glycol through mislabeling or lack of worker training. An absence of quality assurance in the manufacturing process or the failure to observe good manufacturing practices are also important factors in these events.[4]

Malfeasance has occurred in the manufacturing process as well as drug distribution and supply through contamination or mislabeling. Most recent events focused on the practice of "Neutralization" with false representation on labels by brokers or distributors. The practice of purchasing at the lowest price without regard or even inquiry as to quality is also a problem.[5,6] An absent or lax regulatory system enables this detrimental conduct to occur at substantial risk to the public with no liability exposure on the handler's part.

This problem can be framed in several ways. Some would see it as an import/export issue while others look to control through taxation. Those in public health or the pharmaceutical field usually view it as a problem of adhering to standards. In the international arena, however, this is often seen as a case of entrepreneurs in developed countries exploiting the developing world.

A classic case is the mislabeled raw material that originated in China and traveled, at least on paper, through several European countries before arriving in Haiti where it killed children by the score.[6,7,8] Trained scientists quickly identify this as a standards and compliance matter but the remaining 97 percent of the world know this is the "haves" imposing their will on the "have nots". Geography and history supports this position when, after its initial discovery, there has not been a reported incident in the United States or Europe.

Moreover the problem of counterfeit pharmaceuticals with low or no active ingredients is worldwide but most egregious in developing countries. This invidious practice does not get much publicity because brand name pharmaceutical manufacturers dislike negative attention to their products. It is a serious public health concern, however, when citizens believe they are receiving a therapeutic dose but in reality they are consuming a lower dose or a placebo.[10] Merchants in this business are in the odd position of deceiving the poor while stealing from the prosperous by imitating their products.

In any case, it is an international scandal for these deaths to still occur sixty years after the problem was first identified.

What is needed is an international instrument of some kind which would give the rascals engaged in this behavior a very good reason to stop. This issue has attracted the attention of those outside of the public health community, specifically the United Nations Association of the United States of America. This non-governmental organization in its 1997 convention statement adopted the position that "Only through the UN system can we secure a worldwide convention setting safety standards for pharmaceuticals entering international markets, and we urge adoption of one."[11]

It is the responsibility of the leaders on this issue, who are primarily in the public health field, to resolve the matter in a manner acceptable to the international community which goes far beyond the scientific experts. Clearly it would be insufficient to go through the standard setting process, which is essential, and then declare victory.

The next column will feature the results of the Consultation held May 25th through 27th in Geneva.

David R. Work is Executive Director of the North Carolina Board of Pharmacy and is adjunct Professor of Pharmacy Law at the University of North Carolina at Chapel Hill

1. Summary Notes of Discussion Group WHO Geneva July 7-8, 1997.
2. IBID.
3. IBID.
4 IBID.
5. The Killer Cough Syrup, World Press Review,16-17,May1997[NRC HANDELSBAD].
6. Raw Material Tested In Laboratory; Vos Company Knew About Impure Glycerin. NRC Handelsbad, August 2, 1997.
7. Contaminated Medicine Kills 30 Children In Haiti, The New York Times, June 26, 1996.
8. U.S. Has Cast A Blind Eye To Poison Drug Tragedies, The Chapel Hill Herald, February 7, 1997 [NC,USA].
9. China Exported A Sweet Poison...And Haitian Children Paid The Ultimate Price, The New & Observer [Raleigh, NC,USA].
10. "Sixty Minutes", CBS Television News, USA, January 18, 1998.
11. UNA-USA Convention Statement And Resolution On The US-UN Relationship, P8, March 1997.

Pharmacists in the News...

• **Kristy Marie Aswell** of Grantham, a PY3 student at the University of North Carolina School of Pharmacy, is the first recipient of a scholarship given by the Wayne County Pharmaceutical Society which met recently at Wayne Memorial Hospital. Miss Aswell is the daughter of Edward and Mary Aswell. Her goal is to go into community pharmacy.

• At the President's Awards Banquet of the 32nd Annual Alaska Pharmaceutical Association Convention held in Anchorage, Alaska on Feb. 14, 1998, **Capt. Emil L. Cekada** (Ret.) was presented the Senior Pharmacist award for his contributions to health care and pharmacy for all Alaskans. He now lives in Mt. Olive, N.C.

• The N.C. State Legislature passed a bill on May 17th that allows **BlueCross/Blue Shield** to become a for-profit company if it so chooses. If the conversion occurs, 100 percent of its market value will be transferred to a charitable foundation in stock.

• Pharmacist **W.P. "Bud" O'Neal, Jr.** of Belhaven was honored by the North Carolina Hospital Association for his 18 years of service on the board of Pungo District Hospital. In 1992, this owner of O'Neal's Drug Store took over as the Chairman of the Board at a time when the hospital was under financial duress and intense review and sanctions from various regulatory agencies. Under his leadership, Pungo District has flourished to include such services as general surgery, obstetrics, home health, eye surgery, sleep lab and oncology. In 1997, a ground-breaking for a $6 million expansion/renovation project began.

•**Van Weaver** of Raleigh, a member of the American Society of Consultant Pharmacists, was selected to participate in the ASCP Foundation's Disease Pharmacotherapy Traineeship for Consultant Pharmacists. The focus on the traineeship is on management of disease in elderly nursing facility residents, emphasizing unique features of pharmacotherapy.

• **Sandi Bryant** of Asheville was selected to participate in two Parkinson's Disease Pharmacotherapy Traineeships being offered by the American Society of Consultant Pharmacists Research and Education Foundation this year at the Sinai Hospital Clinical Neuroscience Center in Michigan.

• The American Pharmaceutical Association's Academy of Pharmacy Practice and Management installed its new officers at the APhA 145th Annual Meeting this year. **Leanne Kennedy** is chair-elect of the section on Hospital and Institutional Practice. She is clinical coordinator of oncology at North Carolina Baptist Hospital in Winston-Salem. **Joni Berry**, co-owner of Integrated Pharmaceutical Care Systems Inc. and clinical consultant to Hospice Pharmacia Inc. in Raleigh, was elected chair-elect of the section on Specialized Pharmaceutical Services.

• **Lucile Gillespie Brown**, 1943 graduate of UNC School of Pharmacy, died on April 15th at her second home in Burnsville, N.C. She was a pharmacist in Tampa, Fl., Burnsville and later at Holy Cross Hospital in Fort Lauderdale, Fl., where she was chief pharmacist for nine years before joining her husband to develop the Coconut Creek community in Florida. She was one of the first women in Florida to earn a general contractor's license.

• **John Lee Jones Jr.** of Canton, N.C. died on May 25, 1998. He graduated in 1950 from the UNC School of Pharmacy. He owned Canton Drug Store.

•TEVA Pharmaceuticals USA announced that **Sylvia A. Saint-Amand** of Campbell University and **Mike Damofall** of the UNC School of Pharmacy are recipients of the 1998 Outstanding Student Awards.

• Dr. **Tom Holmes**, associate dean, and **Nita F. Johnston**, class president, unveil the Class of 1998 gift to Campbell University School of Pharmacy at graduation exercises. Stephen R. Novak, President, NCSHP, looks on approvingly. The exquisitely framed calligraphic version of the Oath of the Pharmacist (prepared by Anne Amall of Greensboro) is now displayed in the main hallway of the school. (see right)

• Mr. James L. Creech, RPh, was awarded the M. Keith Fearing Community Pharmacy Practice Award at the Campbell University School of Pharmacy Commencement Ceremony, May 11, 1998. Left to right (award luncheon speakers): M.W. Stancil; Mrs. Lib Fearing; Lloyd M. Whaley, RPh; Mrs. Mary Creech Gulledge; James L. Creech, RPh; Ronald W. Maddox, Dean; Mrs. James Creech. (see below)

• PROJECT ImPACT: Community based cholesterol Management program, **King HB III**, Medicap Pharmacy, Wilmington, NC. — Prospective patients for the pharmacy's cholesterol reduction program were identified by computer printouts, in-store posters and brochures. The most effective avenue was advertising in the local paper and on the radio. Notifying selected physicians was least effective; they did not fully understand the program's goals and were reluctant to refer patients. Patients received a Project ImPACT brochure and a letter describing the benefits to the physician, and were required to have their physician sign a "Request for Pharmacy Services" Form.

The Study has 39 patients, 15 male and 24 female. Females seem more interested in their health and the contributions the pharmacist can make. Four of the five dropouts are male. Known reasons include: busy schedule, fear of finger sticks, loss of interest. Six patients are on diet and exercise alone and 28 are on medication. Each received three visits at one-month intervals to assess and get a baseline lipid profile. They were educated about atherogenesis, diet therapy and the importance of being active. Further visits reinforce these points, motivate the patient to listen, focus on the actual lipid profile figures and on the cues that patients give about what they want to talk about and their body language. Learning about the interaction between pharmacist and patient has been a ratifying and pleasant experience.

As of November 1997, 16 patients have reached goal levels of LDL as set by their physician; 18 have not, due to noncompliance or physician reluctant to alter drug therapy — from no drug to a drug or from estrogen or gemfibrozil to a more appropriate statin drug. Monitoring for progress has helped my patients understand why and how to reach their goals for better health.

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OFFICIAL MINUTES OF THE NCPhA BUSINESS MEETING

May 29, 1998

President Jimmy Jackson opened the business meeting at around 8 a.m. on Thursday, May 28, 1998, at the Omni Hotel in Chapel Hill, N.C. He presented his report on NCPhA activities and described accomplishments and opportunities. Currently, NCPhA has 1,555 members. The Convention format was changed this year to facilitate programming, provide more time for educational programming and promote fun and interaction among participants. Dan Garrett has been appointed as Executive Director. Mr. Garrett's excellent experience in pharmacy and dealing with consolidation in his previous job should enable him to provide appropriate leadership to NCPhA. President Jackson indicated that he appointed a Committee to explore organizational consolidation, and he thanked the committees' members for their work. He mentioned that NCPhA's revenue stream comes from membership dues, insurance programs and the Endowment Fund. This Fund has been ignored for several years and has been revitalized this year with the support of Milton Whaley and Keith Elmore. There are several critical needs at the Insitute of Pharmacy including updating technology and building maintenance. The attic had to be finished with sheet rock walls to comply with fire regulations. The Woman's Auxiliary and PNNC each contributed half of the cost of these repairs.

Bylaw Revisions

The Bylaw revisions were introduced at the meeting as shown in Appendix A. The purpose of these changes is to create a treasurer position so that the Executive Director will no longer serve as Treasurer.

Action: Approved the Bylaw changes.

NCPhA Task Force on Membership

Chair William Campbell presented a report on behalf of the Committee. Organizational fragmentation prevents NC pharmacy from achieving optimal effectiveness. Dr. Campbell reviewed the Wisconsin Model and then presented the following resolution:

Move that NCPhA join forces with other North Carolina pharmacy organizations to examine options, identify the appropriate structure and implement a single pharmacy organizational structure in North Carolina.

Action: Approved this motion unanimously. (See full report on page 13)

Museum Committee

Chair of the Museum Committee Milton Whaley presented the final report of his Committee. The Pharmacy Museum has been incorporated into the NC Museum of History. He thanked his Committee members and long-time NCPhA member Elsie Booker whose contributions of pharmacy artifacts were critical in furnishing the exhibit. (See related story on page 32)

Nominating Committee

President-elect Elmore served as chair of the Nominating Committee. He presented a report that included candidates:

President-elect
- Randy Ball,Wake Forest

Executive Committee
- Pam Earnhart, Greensboro
- Henry Herring, Wilmington
- Mike Morton, Greenville
- Lori Setzer, Lewisville
- Gray Stewart, Raleigh
- Davie Waggett, Wilmington

Action: Accepted Report as presented.

Second Business Meeting

May 30, 1998

A brief business meeting was called to order by President-elect Elmore around 11:45 a.m., Saturday, May 30, 1998. The second reading of the Bylaw changes was presented.

Action: Approved the Bylaw changes as presented in Appendix A.

APPENDIX A — PROPOSED CHANGES OF NCPhA BYLAWS

Article II - Duties of Officers

Section 1. THE PRESIDENT: The President shall: (14) Appoint from the Executive Committee an Assistant Secretary to serve in the absence of the Secretary.

Section 3. THE EXECUTIVE DIRECTOR: The Executive Director shall: 1) Serve as Secretary~~-Treasurer~~ of the Association;

Article III - Committees

Section 2: EXECUTIVE COMMITTEE

F. Elect a Treasurer from the Association's active members.

2) Finance Committee-The Finance Committee shall consist of at least four (4) members appointed by the President with the Treasurer serving as an ex-officio member.

~~*Remove*~~ *Add*

Submitted by Steve Caiola

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Patient Counseling: Benign Prostatic Hyperplasia; Part 1: Basic Considerations and Non-Drug Intervention

Gossel

Wuest

Thomas A. Gossel, R.Ph., Ph.D.,
Dean, and Professor of
Pharmacology and Toxicology
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph.,
Pharm.D.
Professor of Pharmacy Practice
University of Cincinnati
Cincinnati, Ohio

Goals. The goals of this two-part lesson are to discuss benign prostatic hyperplasia, and to present information useful in counseling patients.

Objectives. At the conclusion of these lessons, successful participants should be able to:

1. identify the causes and etiology of benign prostatic hyperplasia;
2. exhibit knowledge of the drug and non-drug treatment options, and methods to prevent benign prostatic hyperplasia;
3. show an understanding of the pharmacologic actions and adverse effects associated with drugs used to treat benign prostatic hyperplasia; and,
4. demonstrate an ability to counsel patients on prevention and treatment of the condition.

A professional development program made possible by an educational grant from

SEARLE

Introduction

Enlargement of the prostate gland, benign prostatic hyperplasia (BPH), is reported in almost all older males. By age 50, about 25 percent of them will notice a decrease in the force of their urine stream. The incidence increases to approximately 50 percent by age 75, and 90 percent by age 80. One out of four men living past age 80 will require treatment for this disease. BPH is the second most common cause for surgery in males, after cataracts, with nearly 400,000 surgical procedures performed each year.

Two forms of BPH include: *Pathologic BPH* (microscopic hyperplasia with or without macroscopic enlargement of the prostate, and absence of clinical symptoms) and *Clinical BPH* (hyperplastic prostate with clinical symptoms).

BPH is a progressive disease that is an example of true hyperplasia (increased cell number). The term *hypertrophy* (increased cell size) is inappropriate when describing BPH.

The precise etiology of BPH is unknown. However, the presence of normally functioning testes is necessary for hyperplasia of prostatic tissue. Additionally, estrogens are thought to play a role in its induction and development.

Both the incidence and prevalence of BPH increases with age. The aging process apparently influences testicular, adrenal, pituitary and other hormone levels and may predispose development of BPH.

The Prostate Gland

The prostate gland is a firm but elastic organ that reaches its normal adult size of about 20Gm by age 20. It is the size of a walnut having the consistency of a pencil eraser. Located at the base of the bladder, it completely envelops the proximal urethra (Figure 1).

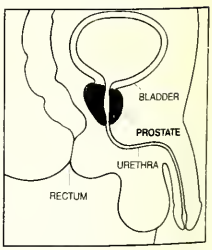
Its purpose is to protect or enhance the functional properties of the spermatozoa. For an average human ejaculate of 3.5mL, the prostate secretes 0.5mL. The gland may also help protect against urinary tract infections through secretion of the prostatic antibacterial factor (PAF).

Two other components of prostatic secretion are acid phosphatase and prostate-specific antigen (PSA). PSA is a protease that helps liquefy the ejaculate. Its concentration is approximately 10 times greater in prostate cancer than in benign tissue, and is the most important marker for prostate cancer.

Prior to puberty, the prostate gland size remains relatively stable. Early in puberty, the gland doubles in size due to androgen stimulation. Around age 25 the gland begins to grow again. This second growth phase often results in BPH years later.

The gland is comprised of an anterior fibromuscular portion and posterior glandular segment. Three morphologically distinct areas of tissue are identified within the latter portion: the peripheral, central and periurethral zones. These are separated by a transition zone.

Hyperplasia is characteristic of BPH and occurs primarily in the periurethral and transition zones. As new cells form and the tissue in this area enlarges, it compresses other glandular tissue, thereby obstructing the bladder outlet.



The Prostate Gland

Role of Testosterone

The principle hormone that regulates both normal and hyperplas-

Table 1
Symptoms of BPH

Obstructive
- hesitancy to initiate voiding
- prolonged dribbling after urination
- sensation of incomplete bladder emptying
- decreased or interrupted stream
- reduced force of urinary stream
- double voiding
- strain or push to urinate

Irritative
- frequency
- nocturia (nighttime urination)
- difficult or painful urination (dysuria)
- urgency
- urge incontinence

tic growth of prostatic tissue is dihydrotestosterone (DHT). BPH does not occur in men who are castrated or who lose testicular function prior to puberty.

In healthy males following puberty, androgen receptors are down-regulated. This means the receptors' reduced sensitivity limits further androgen-stimulated growth. Down-regulation appears to cease in the aging prostate which permits androgen-dependent growth to resume even when there is a decrease in plasma testosterone.

The testes produce testosterone. Synthesis is controlled directly by secretion of gonadotropin-releasing hormone (GnRH). Also referred to as luteinizing hormone-releasing hormone (LHRH), it is a product of the hypothalamic-pituitary gland. GnRH stimulates luteinizing hormone (LH) release which, in turn, binds to receptors in the Leydig cells of the testes where it increases testosterone synthesis. Testosterone is a prohormone for DHT formation in the prostate. Conversion of testosterone to DHT is catalyzed by 5-alpha-reductase.

Symptoms

Although BPH is not a precancerous condition, initial symptoms are identical. Men may suspect BPH as normal for the aging process, but the cause of their reduced urine flow and nighttime urges to urinate, for example, may be prostate cancer. Delayed cancer treatment can have serious results.

Symptoms of BPH are highly patient-specific and variable, and are divided into two categories: obstructive and irritative (Table 1). Obstructive symptoms result directly from narrowing of the bladder neck and urethra. Irritative symptoms result from incomplete bladder emptying or urinary tract infection secondary to prostatic obstruction. The term *prostatism* describes a number of obstructive and/or irritative symptoms of the micturition (urination) process. Most males over 50 experience a combination of the two.

It has been suggested that for clinical symptoms to appear, there must be an additional acute event, such as prostatic infarction (tissue damage from obstructed blood supply).

As the hyperplastic prostate enlarges, it compresses the urethra which obstructs urine outflow from the bladder. The urethra may be blocked partially or completely. In general, one to two percent of men with BPH develop urinary retention.

The detrusor muscle that surrounds the bladder hypertrophies in response to increased resistance. This increased muscle mass can reduce the volume of urine held by the bladder, thus helping aggravate the nighttime urge to urinate. Urinary retention can follow when the muscle no longer generates sufficient pressure to overcome the increased resistance at the bladder outlet.

The extent of bladder obstruction correlates with severity of symptoms. Occasionally the gland will enlarge posteriorly to obstruct the rectum and cause constipation. Over time, symptoms become progressively worse for most men. However, some symptoms improve without surgery or further intervention.

Because the detrusor muscle hypertrophies and becomes more sensitive to irritation, it is more likely to contract spasmodically to initiate irritative symptoms. When irritative symptoms appear in the absence of obstructive symptoms, pathology other than BPH (e.g., cystitis) should be suspected.

The risk of complications with BPH is usually minimal. Complications may include acute urinary retention, serious urinary tract infection, irreversible impairment of bladder function and chronic renal failure secondary to bladder obstruction.

The size of the prostate gland does not always correlate directly with the severity of symptoms, and a clinical diagnosis of BPH is ordinarily not regarded as an immediate threat to the upper urinary tract or to patient survival. Fifty percent of patients with BPH will, over time, become symptomatic.

BPH Diagnosis

A thorough medical history, complete physical examination and urinalysis are necessary in the diagnosis of BPH. Various laboratory tests may rule out other disorders such as prostate cancer. The gland will be found on digital rectal examination to be enlarged. A gland that appears to be normal in size on palpitation may still cause significant bladder outlet obstruction if the tissue around the urethra, which cannot be palpitated, is enlarged. When symptoms are of concern because of their intensity and blockage from other sources has been ruled out, studies should be conducted to evaluate the extent of bladder obstruction.

Maximum urine flow is the parameter most often assessed. Flow rates greater than 15mL/second are in the normal range. Flow rates less than 10mL/second are subnormal. While urine flow rate measurement is useful, some persons may have severe obstruction with normal or near-normal flow rates.

Therapeutic Considerations

Medical assistance is usually sought only when symptoms cause significant discomfort or quality of life is affected adversely. Generally, men are more hesitant to seek medical advice than women, particularly for a condition which may be embarrassing to discuss.

Therapy will not modify underlying pathologic changes, but may relieve or eliminate symptoms. Treat-

ment should be directed toward modifying specific symptoms. It is important to first identify and treat all concurrent conditions that mimic symptoms of BPH prior to initiating therapy for BPH. These conditions can include diabetes mellitus, neurologic disorders, urinary tract infections and renal disease.

Medications with anticholinergic effects which lessen detrusor muscle contractions, or drugs with sympathomimetic effects which block relaxation of the internal sphincter, should be avoided. These include many cough and cold remedies, OTC appetite suppressants, and hay fever products, i.e., antihistamines and decongestants.

Medical treatment commonly involves blockade of alpha-1 adrenergic receptors and reduction of testosterone stimulation. Medical treatment will be covered in Part 2 of this series.

Several other interventions may be helpful in alleviating symptoms. Allowing several uninterrupted minutes to urinate may achieve more complete bladder emptying. The dosage of diuretics should be lowered as much as possible and the drug administered as a single daily dose early in the day. Fluid intake, including beverages with diuretic activity such as alcohol, coffee, tea and colas, should be restricted in the evening to reduce nocturia.

Invasive Intervention

Surgery. Surgery was the mainstay treatment of BPH for many years. When considered, several important issues must be evaluated since neither prostatic hyperplasia nor symptoms of BPH alone are sufficient indications for surgery.

Surgery may be indicated when symptoms are particularly severe; if there has been previous acute urinary retention requiring catheterization; urine flow rate is low; there is increased residual bladder volume; or hydronephrosis (dilation of the pelvic cavity of the kidney caused by obstruction to urinary outflow) with secondary azotemia (accumulation of excessive nitro-genous products in the blood), severe hematuria (blood in the urine), or recurrent, severe urinary tract infection are present. Surgical intervention includes open prostatectomy (excision of part or all of the prostate gland) and transurethral resection of the prostate (TURP).

TURP. Open prostatectomy has been replaced almost completely (in up to 95 percent of patients) by TURP, which is considered a closed procedure because it does not require an open surgical incision. TURP is reported to be the second most common procedure performed in Medicare patients, with an estimated cost which exceeds $5 billion each year. Prostatectomy is reserved for men whose glands are too large for TURP. It will occasionally be performed when additional procedures are required, such as removal of bladder stones.

TURP is performed through the urethra. An instrument called a resectoscope is positioned within the prostatic urethra. The urologist can visualize the obstructing BPH tissue. A wire loop extending from the end of the resectoscope can cut away the obstructing tissue which is rinsed out of the urethra.

TURP is preferred over prostatectomy because it is safer and associated with shorter hospital stays. The period of postoperative catheterization is reduced, and there is less physiologic stress. TURP usually relieves bladder outlet obstruction in up to 90 percent of cases and can increase the urine flow rate to approximately twice its preoperative volume.

Complications include bleeding, infection, incontinence, and impotence. Bleeding requiring transfusion occurred in 2.5 percent of patients in one report. Infection follows in up to 30 percent of postoperative patients.

Incontinence and impotence are the most feared complications of TURP, and reportedly the most often cited reasons for avoiding the procedure. Total incontinence occurs in less than one percent of patients. Sexual dysfunction in five to 35 percent of men has been reported in various studies. If impotence occurs, it will be due to damage to the nerves responsible for erection.

Temporary urge incontinence is common for a short period following surgery. Medications may be given to relax the bladder if this problem is bothersome or persistent. These include flavoxate (Urispas) or oxybutynin (Ditropan, etc.).

Retrograde ejaculation has also been reported. While the sensation of orgasm is maintained, patients may note that it "feels different."

Transurethral Incision of the Prostate. In symptomatic men whose prostate gland is near normal size, TUIP (transurethral incision of the prostate) may relieve urinary obstruction effectively. For the procedure, a deep incision is made through the gland. The extent of improvement of symptoms is the same for TUIP and TURP. TUIP does not result in bladder neck contracture or retrograde ejaculation. TUIP can also be performed under local anesthesia on outpatients. It is not known whether its long-term efficacy is comparable to that of TURP.

Balloon Dilation. Transurethral dilation of the prostate (TUDP) may reduce BPH symptoms. Similar in objective to coronary angioplasty, a balloon is inserted through the urethra into the enlarged prostate. It is expanded to compress the tissue and increase the lumen size, then withdrawn. Its long-term effectiveness is unknown.

Balloon dilation is most effective in patients with mild obstructive symptoms. While safe and free of the complications associated with TURP, its primary disadvantage, at present, is that its effectiveness is unpredictable.

Transurethral Hyperthermia. This procedure is being studied for treatment of outpatients with BPH. It may be especially valuable in men who are poor surgical risks.

A flexible catheter is inserted into the urethra where it emits microwave energy to its targeted tissue. Simultaneously, the catheter also cools and protects adjacent urethral and healthy tissue. The outcome is decreased bladder obstruction with minimal complications. Long-term effects are not known.

Laser Destruction. This procedure directs a laser beam to destroy hyperplastic prostatic tissue. Lasers heat intracellular water to boiling, thereby destroying cells in their path.

Laser treatment offers a shorter recovery period and fewer complications than TURP. Laser therapy may one day offer a treatment alternative that can be performed on an outpatient basis.

Other Techniques. Future treatments may include the use of transurethral stents (implants). In addition, ultrasound-induced aspiration of tissue is being studied.

Summary

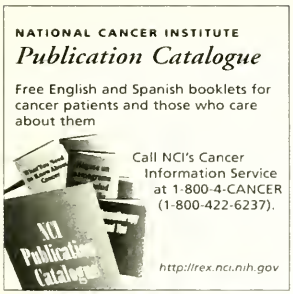
Though a common and normal sequelae of the aging process in men, BPH should not be feared. It can be annoying and cause life-style changes, but it is not precancerous and no study has demonstrated a positive correlation between the two conditions. On the other hand, BPH and prostate cancer share similar symptoms, and patients should seek medical assistance without delay to rule out the possibility of cancer.

Most symptoms of BPH can be controlled with invasive procedures or drug therapy. Either has strong advantages and disadvantages.

Information to convey to patients is summarized in Table 2. Additional points specific to the drug products will be presented in Part 2 of this lesson.

Table 2
Patient Information on BPH

- Tell your doctor about any urinary problem you have, such as difficulty in starting or maintaining a urine stream, getting up at night to urinate, or pain on urination. Sometimes, symptoms may signal other, more serious conditions that require prompt treatment.
- Your doctor may suggest methods to help relieve your symptoms. Be sure to follow those instructions exactly.
- Take all medication your doctor prescribes exactly as directed and do not miss any doses. If you have questions about your drug therapy, talk to your doctor or pharmacist.
- If you notice your symptoms getting worse while taking medication for your condition, or you are concerned about side effects, be sure to talk with your doctor or pharmacist.
- Keep your medication in a tightly closed container and out of the reach of children.
- If you have recently undergone a TURP procedure to increase your ability to urinate, do not take aspirin. If you need a pain killer, an OTC product containing acetaminophen, ibuprofen, ketoprofen or naproxen is acceptable. You can discuss this with your doctor.
- OTC products containing antihist-amines and/or decongestants can worsen your symptoms and interfere with your prescription drug therapy. Be sure to talk to your pharmacist or doctor before taking any OTC product.
- If you must get up at night to urinate, try to limit your fluid intake in the evening. Avoid all beverages and food that contain caffeine, such as coffee, tea, colas, and chocolate.
- When starting to urinate, try to relax and let your urine flow naturally.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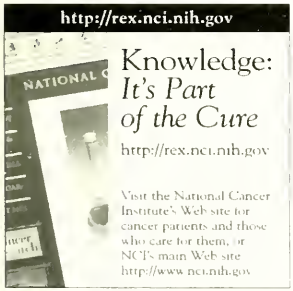
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Continuing Education Quiz

Patient Counseling: Benign Prostatic Hyperplasia; Part 1: Basic Considerations and Non-Drug Intervention

1. The term BPH refers to:
   a. benign prostatic hyperextension.
   b. benign prostatic hyperplasia.
   c. benign prostatic hypertension.
   d. benign prostatic hypertrophy

2. Which of the following statements about the prostate gland is correct?
   a. It is located at the base of the bladder and envel ops the proximal urethra.
   b. It reaches its normal adult size of about 50 grams by age 50.
   c. It produces all of the fluid needed for ejaculation of sperm.
   d. It produces both sperm and testosterone.

3. All of the following are common outcomes of BPH EXCEPT:
   a. incomplete bladder emptying.
   b. the urge to urinate at nighttime.
   c. prostate cancer.
   d. reduced urine flow.

4. The most commonly used surgical procedure for treating BPH is:
   a. open prostatectomy.
   b. transurethral incision of the prostate.
   c. transurethral dilation of the prostate.
   d. transurethral resection of the prostate.

5. The muscle surrounding the bladder that hypertrophies in response to increased resistance caused by BPH is the:
   a. detrusor.
   b. prostatic.
   c. sphincter.
   d. trigone.

6. The conversion of testosterone to dihydrotestos-terone is catalyzed by:
   a. cytochrome P450 oxygenase.
   b. glucose-6-phosphate dehydrogenase.
   c. HMG CoA reductase.
   d. 5-alpha reductase.

7. All of the following are known to be part of the etiology of BPH EXCEPT:
   a. aldosterone.
   b. estrogen.
   c. functioning testes.
   d. the aging process.

8. All of the following hormones are involved in the production of testosterone EXCEPT:
   a. ACTH.
   b. GnRH.
   c. LH.
   d. LHRH.

9. Medical treatment of BPH involves which of the following groups of drugs:
   a. cholinergic blockers and reduction of testoster one stimulation.
   b. beta-1 blockers and increased testosterone for mation.
   c. alpha-1 blockers and reduction of testosterone stimulation.
   d. beta-2 agonists and increased testosterone for mation.

10. Which of the following OTC ingredients causes urinary retention and should be avoided?
   a. Analgesics and antihistamines
   b. Antihistamines and sympathomimetics
   c. Expectorants and sympathomimetics
   d. Vitamin and mineral supplements

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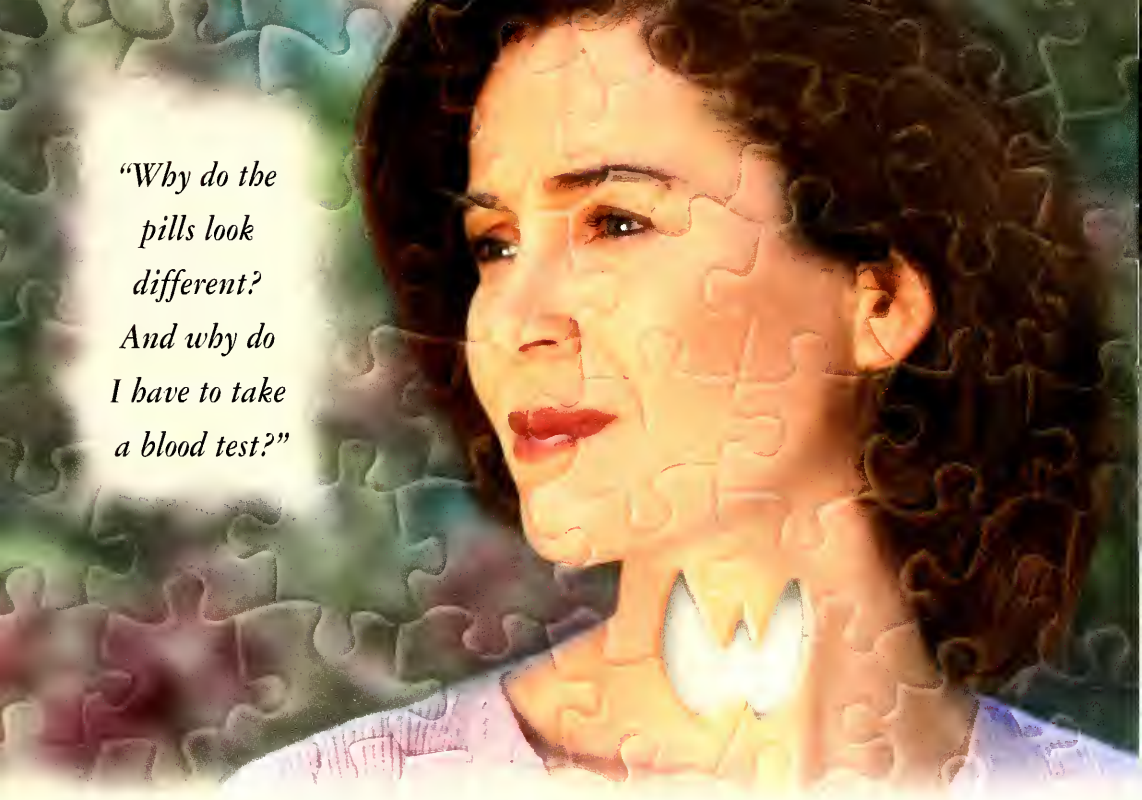

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WARNINGS: Thyroid hormones, either alone or together with other therapeutic agents, should not be used for the treatment of obesity. In euthyroid patients, doses within the range of daily hormonal requirements are ineffective for weight reduction. Larger doses may produce serious or even life threatening manifestations of toxicity, particularly when given in association with sympathomimetic amines such as those used for their anorectic effects.

The use of SYNTHROID in the treatment of obesity, either alone or in combination with other drugs, is unjustified. The use of SYNTHROID is also unjustified in the treatment of male or female infertility unless this condition is associated with hypothyroidism.

PRECAUTIONS: **General**: SYNTHROID should be used with caution in patients with cardiovascular disorders, including angina, coronary artery disease, and hypertension, and in the elderly who have a greater likelihood of occult cardiac disease. Concomitant administration of thyroid hormone and sympathomimetic agents to patients with coronary artery disease may increase the risk of coronary insufficiency.

Use of SYNTHROID in patients with concomitant diabetes mellitus, diabetes insipidus or adrenal cortical insufficiency may aggravate the intensity of their symptoms. Appropriate adjustments of the various therapeutic measures directed at these concomitant endocrine diseases may therefore be required. Treatment of myxedema coma may require simultaneous administration of glucocorticoids (see **DOSAGE AND ADMINISTRATION**).

T_4 enhances the response to anticoagulant therapy. Prothrombin time should be closely monitored in patients taking both SYNTHROID and oral anticoagulants, and the dosage of anticoagulant adjusted accordingly.

Seizures have been reported rarely in association with the initiation of levothyroxine sodium therapy, and may be related to the effect of thyroid hormone on seizure threshold.

Lithium blocks the TSH-mediated release of T_4 and T_3. Thyroid function should therefore be carefully monitored during lithium initiation, stabilization, and maintenance. If hypothyroidism occurs during lithium treatment, a higher than usual SYNTHROID dose may be required.

Laboratory Tests: Treatment of patients with SYNTHROID requires periodic assessment of adequacy of titration by appropriate laboratory tests and clinical evaluation. Selection of appropriate tests for the diagnosis and management of thyroid disorders depends on patient variables such as presenting signs and symptoms, pregnancy, and concomitant medications. A combination of sensitive TSH assay and free T_4 estimate (free T_4, free T_4 index) are recommended to confirm a diagnosis of thyroid disease. Normal ranges for these parameters are age-specific in newborns and younger children.

TSH alone or initially may be useful for thyroid disease screening and for monitoring therapy for primary hypothyroidism as a linear inverse correlation exists between serum TSH and free T_4. Measurement of total serum T_4 and T_3, resin T_3 uptake, and free T_3 concentrations may also be useful. Antithyroid microsomal antibodies are an indicator of autoimmune thyroid disease. The presence of positive microsomal antibodies in an euthyroid patient is a major risk factor for the future development of hypothyroidism. An elevated serum TSH in the presence of a normal T_4 may indicate subclinical hypothyroidism. Intracellular resistance to thyroid hormone is quite rare, and is suggested by clinical signs and symptoms of hypothyroidism in the presence of high serum T_4 levels. Adequacy of SYNTHROID therapy for hypothyroidism of pituitary or hypothalamic origin should be assessed by measuring free T_4, which should be maintained in the upper half of the normal range. Measurement of TSH is not a reliable indicator of response to therapy for this condition. Adequacy of SYNTHROID therapy for congenital and acquired pediatric hypothyroidism should be assessed by measuring serum total T_4 or free T_4, which should be maintained in the upper half of the normal range. In congenital hypothyroidism, normalization of serum TSH levels may lag behind normalization of serum T_4 levels by 2 to 3 months or longer. In rare patients serum TSH remains relatively elevated despite clinical euthyroidism and age-specific normal levels of T_4 or free T_4.

Drug Interactions: The magnitude and relative clinical importance of the effects noted below are likely to be patient-specific and may vary by such factors as age, gender, race, intercurrent illnesses, dose of either agent, additional concomitant medications, and timing of drug administration. Any agent that alters thyroid hormone synthesis, secretion, distribution, effect on target tissues, metabolism or elimination may alter the optimal therapeutic dose of SYNTHROID.

Adrenocorticoids–Metabolic clearance of adrenocorticoids is decreased in hypothyroid patients and increased in hyperthyroid patients, and may therefore change with changing thyroid status.

Amiodarone–Amiodarone therapy alone can cause hypothyroidism or hyperthyroidism.

Anticoagulants (oral)–The hypoprothrombinemic effect of anticoagulants may be potentiated, apparently by increased catabolism of vitamin K-dependent clotting factors.

Antidiabetic agents (insulin, sulfonylureas)–Requirements for insulin or oral antidiabetic agents may be reduced in hypothyroid patients with diabetes mellitus, and may subsequently increase with the initiation of thyroid hormone replacement therapy.

β-adrenergic blocking agents–Actions of some beta-blocking agents may be impaired when hypothyroid patients become euthyroid.

Cytokines (interferon, interleukin)–Cytokines have been reported to induce both hyperthyroidism and hypothyroidism.

Digitalis glycosides–Therapeutic effects of digitalis glycosides may be reduced. Serum digitalis levels may be decreased in hyperthyroidism or when a hypothyroid patient becomes euthyroid.

Ketamine–Marked hypertension and tachycardia have been reported in association with concomitant administration of levothyroxine sodium and ketamine.

Maprotiline–Risk of cardiac arrhythmias may increase.

Sodium iodide (^{123}I and ^{131}I), sodium pertechnetate $Tc99m$–Uptake of radiolabeled ions may be decreased.

Somatrem/somatropin—Excessive concurrent use of thyroid hormone may accelerate epiphyseal closure. Untreated hypothyroidism may interfere with the growth response to somatrem or somatropin.

Theophylline—Theophylline clearance may decrease in hypothyroid patients and return toward normal when a euthyroid state is achieved.

Tricyclic antidepressants—Concurrent use may increase the therapeutic and toxic effects of both drugs, possibly due to increased catecholamine sensitivity. Onset of action of tricyclics may be accelerated.

Sympathomimetic agents—Possible increased risk of coronary insufficiency in patients with coronary artery disease.

Laboratory Test Interactions: A number of drugs or moieties are known to alter serum levels of TSH, T_4 and T_3 and may thereby influence the interpretation of laboratory tests of thyroid function (see **Drug Interactions**):

1. Changes in TBG concentration should be taken into consideration when interpreting T_4 and T_3 values. Drugs such as estrogens and estrogen-containing oral contraceptives increase TBG concentrations. TBG concentrations may also be increased during pregnancy and in infectious hepatitis. Decreases in TBG concentrations are observed in nephrosis, acromegaly, and after androgen or corticosteroid therapy. Familial hyper- or hypo-thyroxine-binding-globulinemias have been described. The incidence of TBG deficiency is approximately 1 in 9000. Certain drugs such as salicylates inhibit the protein-binding of T_4. In such cases, the unbound (free) hormone should be measured. Alternatively, an indirect measure of free thyroxine, such as the FT_4I may be used.

2. Medicinal or dietary iodine interferes with *in vivo* tests for radioiodine uptake, producing low uptakes which may not indicate a true decrease in hormone synthesis.

3. Persistent clinical and laboratory evidence of hypothyroidism despite an adequate replacement dose suggests either poor patient compliance, impaired absorption, drug interactions, or decreased potency of the preparation due to improper storage.

Carcinogenesis, Mutagenesis, and Impairment of Fertility: Although animal studies to determine the mutagenic or carcinogenic potential of thyroid hormones have not been performed, synthetic T_4 is identical to that produced by the human thyroid gland.

A reported association between prolonged thyroid hormone therapy and breast cancer has not been confirmed and patients receiving levothyroxine sodium for established indications should not discontinue therapy.

Pregnancy: Pregnancy Category A. Studies in pregnant women have not shown that levothyroxine sodium increases the risk of fetal abnormalities if administered during pregnancy. If levothyroxine sodium is used during pregnancy, the possibility of fetal harm appears remote. Because studies cannot rule out the possibility of harm, levothyroxine sodium should be used during pregnancy only if clearly needed.

Thyroid hormones cross the placental barrier to some extent. T_4 levels in the cord blood of athyroid fetuses have been shown to be about one-third of maternal levels. Nevertheless, maternal-fetal transfer of T_4 may not prevent *in utero* hypothyroidism.

Hypothyroidism during pregnancy is associated with a higher rate of complications, including spontaneous abortion and preeclampsia, and has been reported to have an adverse effect on fetal and childhood development. On the basis of current knowledge, SYNTHROID® (levothyroxine sodium, USP) should therefore not be discontinued during pregnancy, and hypothyroidism diagnosed during pregnancy should be treated. Studies have shown that during pregnancy T_4 concentrations may decrease and TSH concentrations may increase to values outside normal ranges. Postpartum values are similar to preconception values. Elevations in TSH may occur as early as 4 weeks gestation.

Pregnant women who are maintained on SYNTHROID should have their TSH measured periodically. An elevated TSH should be corrected by an increase in SYNTHROID dose. After pregnancy, the dose can be decreased to the optimal preconception dose.

Nursing Mothers: Minimal amounts of thyroid hormones are excreted in human milk. Thyroid hormones are not associated with serious adverse reactions and do not have known tumorigenic potential. While caution should be exercised when SYNTHROID is administered to a nursing woman, adequate replacement doses of levothyroxine sodium are generally needed to maintain normal lactation.

Pediatric Use: **Congenital hypothyroidism**: Rapid restoration of normal serum T_4 concentrations is essential for preventing the deleterious effects of neonatal thyroid hormone deficiency on intelligence, as well as on overall growth and development. SYNTHROID should be initiated immediately upon diagnosis, and is generally continued for life. The goal of therapy is to maintain the serum total T_4 or FT_4 in the upper half of the normal range and serum TSH in the normal range.

An initial starting dose of 10 to 15 mcg/kg/day (ages 0-3 months) will generally increase serum T_4 concentrations to the upper half of the normal range in less than 3 weeks. Clinical assessment of growth and development and thyroid status should be monitored frequently. In most cases, the dose of SYNTHROID per body weight will decrease gradually as the patient grows through infancy and childhood (see Table). Prolonged use of large doses in infants may be associated with later behavior problems.

Thyroid function tests (serum total T_4 or FT_4, and TSH) should be monitored closely and used to determine the adequacy of SYNTHROID therapy. Normalization of serum T_4 levels is usually followed by a rapid decline of TSH levels. Nevertheless, normalization of TSH may lag behind normalization of T_4 levels by 2 to 3 months or longer. The relative elevation of serum TSH is more marked during the early months of therapy, but can persist to some degree throughout life. In rare patients TSH remains relatively elevated despite clinical euthyroidism and age-specific normal levels of total T_4 or FT_4. Increasing the SYNTHROID dosage to suppress TSH into the normal range may result in overtreatment, with an elevated serum T_4 level and clinical features of hyperthyroidism, including irritability, increased appetite with diarrhea, and sleeplessness. Another risk of prolonged overtreatment in infants is premature cranial synostosis.

Assessment of permanence of hypothyroidism may be done when transient hypothyroidism is suspected. Levothyroxine therapy may be interrupted for 30 days after 3 years of age and serum measurement of T4 and TSH levels obtained. If T_4 is low and the TSH level is elevated, permanent hypothyroidism is confirmed and therapy should be re-instituted. If T_4 and TSH remain in the normal range, a presumptive diagnosis of transient hypothyroidism can be made. In this instance, continued clinical monitoring and periodic reevaluation of thyroid function may be warranted.

Acquired hypothyroidism. The initial dose of SYNTHROID varies with age and body weight, and should be adjusted to maintain serum total T_4 or free T_4 levels in the upper half of the normal range. In general, in the absence of overriding clinical concerns, children should be started on a full replacement dose. Children with underlying heart disease should be started at lower doses, with careful upward titration. Children with severe, long-standing hypothyroidism may also be started on a lower initial dose with upward titration in an attempt to avoid premature closure of epiphyses. The recommended dose per body weight decreases with age (see Table).

Treated children may resume growth at a rate greater than normal (period of transient catch-up growth). In some cases catch-up growth may be adequate to normalize growth, however, in children with severe and prolonged hypothyroidism, adult height may be reduced. Excessive thyroxine replacement may initiate accelerated bone maturation resulting in disproportionate advancement in skeletal age and shortened adult stature.

Assessment of permanence of hypothyroidism may be done when transient hypothyroidism is suspected. Levothyroxine therapy may be interrupted for 30 days and serum measurement of T_4 and TSH levels obtained. If T_4 is low and the TSH level is elevated, permanent hypothyroidism is confirmed and therapy should be re-instituted. If T_4 and TSH remain in the normal range, a presumptive diagnosis of transient hypothyroidism can be made. In this instance, continued clinical monitoring and periodic reevaluation of thyroid function may be warranted.

ADVERSE REACTIONS: Adverse reactions other than those indicative of thyrotoxicosis as a result of therapeutic overdosage, either initially or during the maintenance periods, are rare (see **OVERDOSAGE**). Craniosynostosis has been associated with iatrogenic hyperthyroidism in infants receiving thyroid hormone replacement therapy. Inadequate doses of SYNTHROID may produce or fail to resolve symptoms of hypothyroidism. Hypersensitivity reactions to the product excipients, such as rash and urticaria, may occur. Partial hair loss may occur during the initial months of therapy, but is generally transient. The incidence of continued hair loss is unknown. Pseudotumor cerebri has been reported in pediatric patients receiving thyroid hormone replacement therapy.

OVERDOSAGE: Signs and Symptoms: Excessive doses of SYNTHROID result in a hypermetabolic state indistinguishable from thyrotoxicosis of endogenous origin. Signs and symptoms of thyrotoxicosis include weight loss, increased appetite, palpitations, nervousness, diarrhea, abdominal cramps, sweating, tachycardia, increased pulse and blood pressure, cardiac arrhythmias, tremors, insomnia, heat intolerance, fever, and menstrual irregularities. Symptoms are not always evident or may not appear until several days after ingestion.

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Closing dates for classified advertising is the first day of the month preceding the month of issue. The rate for NCPhA members is .25¢ a word with a $5 minimum; the non-member rate is .50¢ a word with a $10 minimum. Blind ads are available upon request. Send ads to Carolina Journal of Pharmacy, c/o NCPhA, P.O. Box 229, Chapel Hill, NC 27514-0229 or fax to 919-968-9430.

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- The new header record required for NC Medicaid Batch electronic billing to EDS has been implemented.
- The patient now may be indicated as EXEMPT from the limit of six if you have a letter on file.
- Diagnosis codes were added to the patient record.
- The ability to build sigs from partial sigs and whole words intermixed was added.
- Security measures were added to prevent charging to unauthorized customers.
- Multiple third parties may be added to the customer record and the primary third party serves as the default. Secondary third parties may be billed in batch or individually by indicating the prescription numbers and dates.

  When billing a second third party such as Medicaid, you may indicate what the other payor amount was. The new rebilling function makes retroactive Medicaid billing a cinch.
- The entire MediSpan drug file (total file) was added. This file is updated and added to each week. You can add new drugs to your system drug file anytime you wish, even during a refill, by typing in the new NDC and the drug will be instantly pulled from the total file.
- Multiple user-defined tax rates were added.
- Acquisition drug costs now appear on the prescription filling screen.
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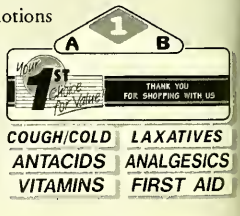

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COVER: The cover features Carmelita lounging at the Carnivore Preservation in Pittsboro, N.C. Mark Kostich, a photographer specializing in nature and wildlife, provided this incredible shot. It will be featured in the CPT Calendar for 1999. (See related story on CPT on page 9.)

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Daniel Garrett, Executive Director

"When you come to a fork in the road, take it!"

Yogi Berra

I am happy to report we had a problem for this journal. We had so many new members to list that we had to scramble to make all the articles fit. This is the kind of challenge we need.

Everyone I meet asks, "How is your new job?" The short answer is — overwhelming! This is the kind of challenge that the Association needs.

Having many new members and being overwhelmed by opportunities indicates that the *spirit* of our profession is alive and well. In my interviews with the Executive Committee, I was asked what would be my first priority. It is and always will be to awaken and tap into the *spirit* of pharmacists who are motivated to advance their practice and better serve their patients. We have had an incredible response to our membership drive. One pharmacist included the following comments on her application, "Thanks for the membership drive. I had hesitated in joining previously; I was not impressed with the Association's services, attitude of progressiveness, etc. Now with the certificate programs on disease management and initiatives on reimbursement for cognitive services it is a different story. Thanks for taking the reins and whipping some life into a near-dead organization." What is exciting to me about this response is that all we did was report on what pharmacists are doing and asked others to join.

The NCPhA Executive Committee and NCSHP Board Members are visiting local pharmacy association meetings and sharing the vision and strategic plans for unifying pharmacy organizations in our state. We have been to meetings in Williamston, Gastonia, Asheville, Greensboro, Monroe, Elizabeth City, Lumberton and Jacksonville just to name a few. Please contact Teressa Reavis in the NCPhA office to arrange for a Board Member to provide an update at your next meeting. A grant from Roche is providing for NCCPC programs on innovation in Waynesville, New Bern, Concord, Greensboro and Chapel Hill. We participated in orientation for pharmacy students at Campbell and UNC. What we have discovered in each of these settings is that pharmacists in all practice sites share a common spirit to unite the profession and speak with one voice.

This issue of the Journal focuses on technology. NCPhA president Keith Elmore describes the Association's commitment to moving forward with a new computer system for our organizations to prepare for serving an expanded and diverse membership. The NCSHP and NCPhA Communications and Public Relations Committees are working together to plan a web site for North Carolina Pharmacy in 1999. The article on Patient Communications Insights offers you the opportunity to learn about yourself and discover a tool which will increase your effectiveness as a patient counselor. Year 2000 preparations are presented by Elizabeth McGuffey, and there is an article in the NCSHP section on the use of robotics at Pitt County Memorial Hospital in Greenville.

We have come as a profession to a "fork in the road." We are moving forward with new practice models, unification and technology. Thanks for joining together to "take it!"

On-Line and In Touch

Don't forget that the NCPhA staff is easily accessible on the Internet. Drop us an e-mail anytime.

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President's Perspective

by W. Keith Elmore

In keeping with this month's Journal theme of technology, I thought it would be timely to relate two areas of technology that the Executive Committee recently voted to pursue.

First, we have decided to enter into an agreement to co-market a software program called ***Patient Communication Insights***. This program will enable the user to more effectively communicate with his or her patient by defining the communication style of the patient. Better communication should result in more successful care, so this technology should benefit the patient as the recipient of pharmaceutical care as well as the pharmacist provider.

The second area of technology has to do with the Executive Committee's commitment to upgrade the Association's hardware and software capabilities at the Institute. We recognize that in order to provide the kinds of member services needed to make NCPhA an effective, relevant professional association, more sophisticated computer technology is essential. To that end, we have voted to fund the purchase and installation of the iMIS management system. iMIS is a comprehensive relational database system which includes modules such as membership management, committee management, activities tracking, meetings management, dues billing, accounts receivable, legislator tacking and more. It has tremendous expansion capability and will greatly increase the efficiency and productivity of our staff. [The office will upgrade hardware to a fileserve PC network.]

I'm excited about the opportunities these two areas of technology present to our Association. I believe both will enable NCPhA to provide its members [Including the long list of new members mentioned to the right] more and different ways to improve patient care.

Olympic track and field champion Jackie Joyner-Kersee has said, "It is better to look ahead and prepare than to look back and regret." In making this commitment to technology, we are looking ahead and preparing for the increased role of the pharmacist in patient care and the assistance that your professional association can give in providing that care.

Bienvenido *Wilkommen* 歡迎

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NCPhA NEW MEMBERS

Will Pharmacy Be Ready for the Year 2000?

by Liz McGuffey, RPh, PhD

Y2K, or the Year 2000, may wreak havoc for many of the systems we now take for granted. For example, who would imagine that on Jan. 1, 2000, our favorite ATM might malfunction? Or that elevators won't run? Or that your automatic thermostat may sense July weather on a cold winter day and may activate the air conditioning? These are all examples of computerized systems which utilize the parameter of time in operating programs and could conceivably shut down or function incorrectly when the Year 2000 presents an unrecognized or ambiguous date.

Are these doomsday predictions realistic? Probably not. But why is Y2K getting so much attention? The root of the Y2K problem stems from the use of the MMDDYY format for dates. Presumably, this shortcut saved memory and processing costs in the early development of computers when computer memory was small and data storage was expensive. It is unclear how futurists of the past could have been so myopic to think that computers would not be in use in the next century and that a MMDDYY format would be problematic.

And what relevance does Y2K have for the practice of pharmacy? Several aspects of computerized pharmacy activities are overtly date-sensitive, whereas others may be susceptible but not so obviously. For example, date of birth and drug expiration dates are clearly sensitive to time parameters. Systems must be able to differentiate between birth years 1900 and 2000 to avoid processing errors, such as discounts and insurance coverage denials, to name just a few. Pharmacists have possibly already run into a problem of entering a drug expiration date beyond 1999 if their systems fail to recognize the Year 2000. In North Carolina and most other states, a prescription is valid only for one year from the date written. As early as Jan. 1, 1999, (not so far in the future!), pharmacy systems must understand that a refillable prescription written on Jan. 1, 1999, will be effective through Jan. 1, 2000.

Other pharmacy applications not so obviously affected by date include compliance programs, DUR interventions and other clinical applications, inventory replenishment programs, third party processing, point of sale systems and accounting programs. The amount of time pharmacists spend today overriding false positive DUR alerts may pale in comparison with that required if computers cannot accurately read the date. Not just over- or under-utilization DURs will be affected, but potentially serious drug interactions may also be missed if cutoff dates are misinterpreted by DUR software. Almost every aspect of pharmacy operation is date-sensitive, and patient care, as well as disruption of daily routine, may suffer if computer upgrades or replacements are not performed in a timely fashion.

The implementation of either upgrade or system replacement requires training. Ronald L. Fine of the Condor Corporation warns users to plan ahead. The process of establishing new procedures can be more time-consuming than expected, particularly in organizations like chain drug stores with central management systems.

How can you know if your system is compatible with Y2K? Ask your computer consultant. Some upgraded systems require dates to be entered in a MMDDYYYY format, as opposed to a MMDDYY format, but an eight-digit date format is no guarantee that your operating system will recognize the Year 2000. In addition, some upgraded systems have hidden codes to "interpret" dates using the six-digit format. In other words, date formatting may not indicate if a system will correctly handle the date beyond Dec. 31, 1999. You should have your computer system checked by a professional and the sooner the better.

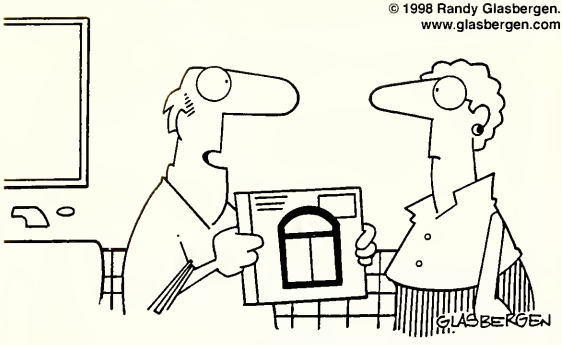
Most BIOS (Basic Input Output Systems) in computers sold before 1994 and some sold after 1994 will not correctly handle dates beyond Y2K. Some systems can be upgraded, others cannot and must be replaced. Programs that check whether your computer's BIOS will correctly read Jan. 1, 2000 are available. Check with your computer consultant.

Jim Hall of VIP Computer Systems in Hillsborough, NC states that all of his systems in current operation are compatible with Y2K. He warns others that a 586 or better processor will probably handle Y2K without problems, but 486 processors should be investigated.

In spite of serious computer shutdowns on Jan. 1, 2000 predicted by some doomsdayers, pharmacy programs are less likely to be affected than some long-standing government programs. Pharmacy computers first appeared in the mid-1980s, whereas some government programs still in operation today were developed in the 1970s. Date coding may be concealed in older programs that were written in language obsolete today and unknown to present programmers. Analysis and correction of older programs to be compatible with Y2K is a tedious, time-consuming task, but a computer programmer's financial windfall. One organization has estimated that the repair-replacement bill to make every computer Y2K compliant will be $600 billion worldwide by the end of year 1999.

Fortunately for pharmacy and its rapidly evolving role in providing pharmaceutical care, pharmacy computers are relative newcomers with easy upgrades. However, since computers control practically all aspects of the practice of pharmacy, pharmacists should make sure that their systems are compatible with Y2K. And the time to act is now.

For more information on Year 2000 problems, check out web site **www.year2000.com** *or the book* **Managing 00:Surviving the Year 2000 Computing Crisis** *by Peter de Jager and Richard Bergeon. Many recent books and numerous other web sites also address Y2K problems.*



"I bought a computerized bathroom scale. On January 1, 2000 it will change our weight back to zero!"

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Ron Davis, Buford Road Pharmacy, Richmond, VA

"The GNP+ program has helped me return to my profit levels of a few years ago. I can economically do much more and act like a chain, but I still run my store to fit my local market."
Gary Dreyfus, Moulton Plaza Pharmacy, Laguna Hills, CA

"The advertising for Good Neighbor Pharmacy has really had an impact. Bergen Brunswig has put forth the maximum effort to help us succeed. When the Good Neighbor Pharmacy Across America promotional bus came to town, it really reinforced that we are part of a powerful group."
Tom Neale, Pharmacy Plus, Teague, TX

"Chain drug stores have been expanding rapidly in the Southeast. But Good Neighbor Pharmacy Plus cluster groups have been able to make independents competitive again. We realized we are connected and have the resources to grow our business."
Robert Sopocy, Family Drug Mart, Port St. John, FL

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GOOD NEIGHBOR PHARMACY

EYE ON THE TIGERS: N.C.'s CARNIVORE PRESERVATION

On 55 acres of sprawling land in Pittsboro, N.C., Carmelita (see cover photo) and 260 of her fellow meat-loving friends are living the good life at the Carnivore Preservation thanks to a common mission and many caring volunteers.

The Carnivore Preservation Trust is a non-profit organization devoted to the preservation of wild animals from tropical ecosystems. The major programs involve education activities in both the United States and developing countries, captive breeding of endangered species, wild animal rescue and assistance activities. CPT was founded in 1981 by Dr. Michael Bleyman, a former professor at UNC-Chapel Hill. He developed the concept of a genetic preserve of endangered species perpetuated over many generations using captive breeding and education. The original idea was to hold the animals in the United States until there was a safe habitat to return them to.

In 1992, CPT began setting up a conservation center in Laos. The Laotian project provides a very tangible connection to the problem of wildlife conservation, the environment and to cultures and people living a very different way of life. The animals in North Carolina have a connection to their original habitat, and there is hope that their habitat will be saved for the future. It also allows unique education opportunities for volunteers and students associated with CPT. Since 1995, 15 individuals have volunteered at our Laotion operation for up to 12 months and have received valuable experience in wildlife conservation, animal care and rehabilitation.

People become involved with CPT for many reasons. They truly do come from all walks of life. Certainly most have a love of animals and a desire to work with them. Some have a fascination for the big cats and want to help preserve them in humane conditions. Others are extremely troubled by the number of wild animals being kept in cruel conditions and want to rescue them. CPT attracts some people who are disturbed by the trend that projects the destruction of a great majority of tropical forest areas in our lifetimes.

CPT relies entirely on volunteers for accomplishing its mission. It hosts volunteers for every part of its operation and is mostly supported by tax deductible donations of services and materials to keep the organization running. CPT is currently seeking volunteers, medical supplies, equipment and cash donations in order to equip and supply a veterinary clinic that is now under construction.

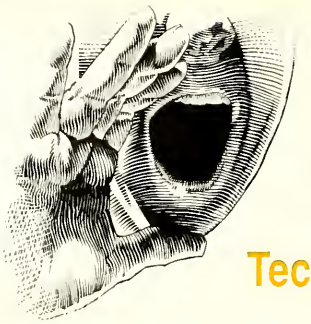
This year CPT is adding a veterinarian to the permanent staff. This new position enhances the ability of CPT to establish a veterinary and zoology career mentoring program and other new education activities. While providing better care and improving the overall health of our animal collection, it also offers enrichment and supervision for students who participate in the program. CPT provides internship opportunities for zoology students from across the state particularly for students from Duke, NC State and UNC-Chapel Hill. CPT will be able to provide more and better educational activities for these students with the recruitment of a staff veterinarian. Approximately 120-150 interns will participate in the program this fiscal year. CPT plans to establish an exotic animal externship program for veterinary students, with NC State students being given priority for acceptance into the program. With the addition of the veterinary externship program, CPT will serve more than 250 students from high school through graduate school each year.

Providing education opportunities to people in North Carolina has always been a major aspect of CPT's mission. In-school education programs have been growing and expanding since 1986, reaching more than 5,000 children each year. CPT serves students and teachers of all ages who want to learn about wildlife and conservation with a science class or course being offered at their school or university. Last year, the Carnivore Preservation joined forces with the Carolina Raptor Center in Charlotte to develop an environmental education workshop for middle school teachers. This workshop will allow for expansion of educational reach to thousands more children each year.

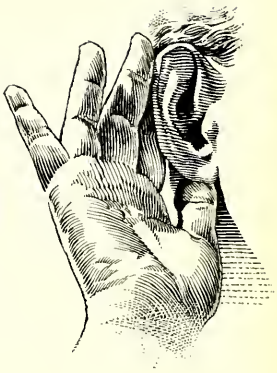
CPT is in a special position to be able to provide both hands-on experience working with animals and to reinforce that training with specialized materials developed for that purpose. In addition, the staff has years of experience training new people and is always available for questions and consultation. Because of the long experience in training volunteers and the intensive contact with the animals, CPT can offer students an unparalleled opportunity to work with every aspect of exotic animal husbandry. Students receive much more hands-on experience with the animals than a zoo can provide. In addition, because it is a breeding facility for certain targeted species, CPT offers a unique opportunity for studies involving access to many animals of one species for comparisons. Since animals are kept throughout their lifetimes, students can conduct long-term studies. Unlike a veterinary clinic, students will have the opportunity to work with animals that are well and in their normal environments as well as the injured or sick.

Interested people are welcome to call and arrange a visit to CPT. Visits are only by appointment and conducted on Saturdays and Sundays. If you are interested in volunteering or donating to CPT, please call (919) 542-4684 or send for more information at CPT, 1940 Hanks Chapel Rd., Pittsboro, NC 27312.

Also, the 1999 CPT Calendar is $16 including NC sales tax plus $3 shipping and handling for the 1st calendar and $1.00 for each additional one. All proceeds from the calendar support CPT operations. Order by VISA or Master Card or mail check to CPT. (See previous paragraph for address and phone number.)



Communicating for Excellence: Techniques for Counseling Patients



by Stephanie Barnard, Communication Consultant

Imagine this scenario: Mrs. Smith, a 73-year-old woman who has just been diagnosed with Type 2 diabetes, comes into the pharmacy to fill her prescription for acarbose. She has always eaten whatever she wants, she is afraid to check her blood glucose, and she has a mini-battle going with her internist because she thinks "a little bit of sugar won't hurt a thing."

All pharmacists have experienced this kind of scenario. The outcome for Mrs. Smith depends on how well her health care providers (the physician, registered nurse, certified diabetes educator and pharmacist) educate her about diabetes. Because of time constraints in the physician's office, often the task of educating patients falls on the pharmacist.

Now it's your turn. How do you help Mrs. Smith without discouraging her? With all of these issues, where do you start?

With all of the advances in science and technology, one thing still separates the competent from the outstanding: good communication skills. No matter how well pharmacists understand the mechanism of action of a drug in the body, the way they explain it to patients is how they are judged.

This article offers specific techniques pharmacists can use to communicate more clearly with patients. Incorporating these techniques into your communication style will render many positive results: your patients will comply with your recommendations, your colleagues will notice your results and adopt your ideas, and your job satisfaction will improve.

Listening to Understand

One of the most important components of good communication is the one we ignore the most: listening. Listening requires us to not only hear what the other person is saying but to comprehend it as well. Some tips for effective listening are:

o Make eye contact: try to focus on the other person's face throughout the conversation
o Smile, nod and acknowledge: others notice your behavior when they are talking and adapt theirs accordingly
o Echo what others have said to show you are paying attention. Example: "I understand that you are concerned about..."

Speaking Clearly and Concisely

In our mind's eye we are all great communicators. To our listeners the style we choose may not be as clear. Test your speaking skills by listening to yourself on voice mail at least once a month or tape recording your patient consults (with the patient's permission). When you play the recording back, you may be surprised at the unnecessary or confusing words you choose.

The following tips offer techniques for speaking more clearly:

o Speak in specific, concrete terms. Replace "eat better and exercise" with "eat X, Y or Z in moderation and walk one mile every day." Choose "I'll be finished at 4 p.m." over "I'll be finished soon."
o Select positive words. Replace "you better" with "I suggest" and avoid negative words such as "don't," "won't" or "didn't" after the word "you."
o Make yourself aware of tone: Watch for a rise in your voice when you become annoyed and avoid wit and dry humor as it may be confused with sarcasm.
o Use laymen's terms to describe medications, diagnoses, and treatments. Example: Choose "fluid pill" instead of "diuretic."
o Use the least amount of words possible to illustrate a point. Example: Choose "now" instead of "at this point in time."
o Select words that have fewer syllables. Example: Use "some" instead of "proportion."

Sharpening the Patient Consult

The following tips represent a collection of techniques gathered from pharmacists, health care professionals and

patients. These techniques offer specific ways to increase patient compliance and satisfaction, therefore leading to positive outcomes.

1. Greet patients with a handshake or pat on the shoulder, make eye contact and smile. Eye contact and non-sexual physical contact allow you to appear more attentive and sincere.

2. Introduce yourself, explain who you are and use patients' names. Taking the time to explain who you are will foster your relationship and increase patient compliance. Repeating patient names will help you remember the names later.

3. Start patient counseling with brief general conversation such as "How may I help you today, Mrs. Smith?" This "breaks the ice" and allows patients to ease into the conversation.

4. Invite requests and respond to questions appropriately. Resist the desire to interrupt patients.

5. Maintain eye contact throughout the conversation by rotating where you look on patients' faces. Rotate from the eyes to the nose, etc.

6. During the consult, demonstrate genuine interest and concern for the patient. Patients respond to pharmacists who appear to care about their health.

7. Strive to reassure the patient about the diagnosis, treatment or outcome. Most patients need reassurance in order to deal with the situation.

8. During the consult, inquire about personal issues such as work, family, etc. and make notes in your files on areas you need to remember for the next visit. Patients are impressed with pharmacists who seem to care about their personal lives. You may also learn key information about the patient's care.

9. If you have trouble responding to a comment or question (especially a negative remark), repeat the question or comment back to the patient. It shows patients you have listened, gives you time to formulate an answer, and diffuses the patient.

10. Take patient concerns seriously— no matter how trivial. Give patients brochures, videos and other information to help them understand a treatment or prescription. Offer your business card to patients with an opportunity to call you later with additional questions. Patients take their health seriously and expect you to do the same.

11. Explain the disease state, the mechanism of action, the prescription information and other instructions in detail and in layman's terms. If possible, draw diagrams for the patient and give out brochures. Visual aids increase comprehension and retention.

12. Speak to patients in the same tone as you speak to peers. Most people appreciate advice from a peer rather than a "parent."

13. Allow patients to voice concerns before you address prescription information. Patients will listen better after they have absorbed the diagnosis.

14. Explain why to patients: why a certain procedure will work, why they should take their medication, etc. This technique increases patient compliance and satisfaction.

15. Offer patients a chart, calendar or system for taking medications. Patients will comply with easy-to-understand instructions.

16. Do not be afraid of physical contact: sit down beside patients and touch their hands when you speak to them; give patients a pat on the back or hand when they are leav-

Challenging Yourself to Be a Better Communicator

The best way to sharpen your skills as a communicator is to change your behavior. Try a new communication challenge every two weeks and watch the positive results.

1. The Eye Contact Challenge
Eye contact is the most powerful nonverbal tool you own. Master it. For at least two weeks, practice sustaining eye contact in casual conversation. Rotate where you look on the other person's face and that person will think you are making eye contact the entire conversation.

2. The "Um" Challenge
Without even realizing it, most people say "um" several times in a conversation. Unfortunately, "um" has no meaning. In fact saying "um," "you know," "anyway," "sort of" and other fillers often distract the listener from your real message. Practice not saying "um" by pausing instead. Your listener will appreciate the brief silence.

3. The Listen-to-Yourself-On-Voice-Mail Challenge
At least once a month, listen to yourself on voice mail. Once you get over the shock of hearing your own voice, you can assess whether or not your messages are clear, concise and positive. You will also hear the unnecessary "ums."

4. The Public Speaking Challenge
One of the biggest fears people have is public speaking. Perhaps this is why we are so impressed with colleagues who do it well. Professionals who can stand up in front of a crowd and deliver an organized, clear message will always rise to the top. Start small: speak up at a professional society meeting or offer to do an in-service at a local nursing facility. Then move on to more challenging audiences, such as a group of nurses, pharmacists or physicians.

ing. — Patients view non-sexual physical contact as reassuring and comforting.

Recognizing Your Benefit

By adopting more effective communication techniques, you can help Mrs. Smith control her blood sugar while improving your practice, an outcome that benefits everyone.

Stephanie Barnard owns Business Image Consulting, Inc., a public relations firm in Columbia, S.C. She has consulted for medical practices, long-term care facilities and pharmacies and other health care organizations. As a communication consultant for Bayer Corporation, Pharmaceutical Division, Ms. Barnard teaches seminars for the Writing and Speaking for Excellence educational series. This series, sponsored by an educational grant from Bayer Corporation, offers seminars on communication for pharmacists, physicians and other health care professionals. For more information on these seminars, call Ms. Barnard at 803-699-2633 or Deborah St. James of Bayer Corporation at 203-812-6357.

Dealing With Upset Patients

Most health care professionals deal with upset patients on a regular basis. The best way to understand what an upset person wants is to recall the last time you were the upset person. What did you want the person to whom you were complaining to do?

Listen. Avoid making excuses. Fix the problem — fast. The following checklist offers concrete techniques on how to deal with an upset person, step-by-step.

1. Remain silent. Wait for the other person to speak before you comment.

2. Echo what has been said. Rephrase what the other person has said in order to:
   - o Show you are listening
   - o Clarify the problem
   - o Show the person how he/she sounds

3. Make an intention statement. After listening and waiting for the other person to finish, the first words you speak should express intent. Example: "It's not our intent to upset you, Mrs. Smith. We want to deliver on our promise."

4. Offer a solution while giving the upset person a choice.
Example: "I am sorry we are running behind. Would you like to come back for your prescription after lunch or on your way home from work?"

Golden Opportunities for Pharmacists

by Linda Cross

During the month of October, pharmacists in North Carolina have a golden opportunity to stake their claim as integral players in health care delivery. First, National Pharmacy Week (October 18-24) is your opportunity to be recognized for all that you do. Second, October has been designated as "Attack Asthma Month." (Note the change from September to October.) The American Lung Association of North Carolina, the North Carolina Thoracic Society, the North Carolina Division of Women's and Children's Health and Glaxo Wellcome have partnered to promote asthma awareness statewide for the entire month.

The statistics concerning the prevalence of asthma in North Carolina are astonishing. One in every 18 children may suffer from the disease and nearly 30 percent of all who suffer from asthma are unaware of how to prevent attacks or how to manage the illness when attack occur. Episodes of uncontrolled or poorly controlled asthma are costly in terms of dollars and human suffering. And now North Carolina pharmacists have an opportunity to make a difference.

You can take advantage of this publicized promotion by taking a proactive attitude to position pharmacy in its rightful place as an integral part of the health care delivery system, especially in the area of asthma management and education. Use this opportunity to offer your expertise to your patients who suffer from asthma, especially young children. When your patients know they can turn to you for sound advice concerning asthma, they will become more willing to seek your advice for managing other chronic and acute illnesses.

Rarely are we afforded such an opportunity to do something so positive for our profession. Don't miss this chance!

Linda Cross is Manager of Drug Utilization Review for the North Carolina Division of Medical Assistance and NCPhA Public/Professional Relations Chairperson.

Welcome Class of 2002

University of North Carolina, Chapel Hill, N.C.

On Monday, August 17th, the University of North Carolina School of Pharmacy welcomed its newest class of pharmacy students with a day-long orientation and a barbecue luncheon sponsored by the UNC Pharmacy Alumni Association. There were 124 applicants admitted to the School of Pharmacy for the 1998-99 school year. Approximately 73 percent of the first-year class transferred to the School of Pharmacy from within the University, while 27 percent were admitted from other institutions.

This year's incoming class continues the School's tradition of academic excellence, as approximately 12 percent of PY1 students were valedictorians or salutatorians of their high schools. The class also illustrates students are more racially diverse than students at the University as a whole, with 22 percent verses 19 percent minority enrollment. PY1 students also come in with a wide variety of life experiences and range in age from 19 to 42. There are 87 women in the first year class (70 percent of students) and 37 men.

The School of Pharmacy currently enrolls a total of 435 students, 99 of whom are performing their rotations this year and will be graduating in May. These newly-minted graduates will form the first class of the second 100 years of UNC School of Pharmacy graduating classes, and they will be following in the impressive footsteps of the over 5,300 UNC School of Pharmacy alumni who currently serve their communities.

Campbell University, Buies Creek, N.C.

Jack G. Watts of Tabor City and Burlington, past-president of the North Carolina Board of Pharmacy (1993-98) and past-president of the North Carolina Pharmaceutical Association (1980-81), was recognized on Sept. 1, 1998, by Campbell University with the honorary Doctor of Science degree. Jack, along with his wife Eloise, was recognized at the University Convocation Ceremony for his long and productive service to the profession of pharmacy and his community. A host of pharmacy dignitaries enjoyed this recognition and celebrations of Dr. Watts' accomplishments.

Jack G. Watts received his pharmacy degree from the University of South Carolina in 1955. He worked as a sales representative for Eli Lilly and Co. for 31 years with additional pharmacy practice in both the retail and hospital sectors. After retirement from Eli Lilly, Jack became affiliated with the Greensboro Area Health Education Center of the Moses H. Cone Memorial Hospital. He has served as an Adjunct Professor of Pharmacy Practice at Campbell University and Clinical Associate Professor at the University of North Carolina School of Pharmacy.

Dr. Watts was recognized as the Alamance County Pharmacist of the Year in 1985 and the North Carolina Pharmacist of the Year in 1986. He was honored with the NCPhA A.H. Robins "Bowl of Hygeia Award" for outstanding service as a pharmacist in 1992. As a long-time Trustee of Campbell University, Dr. Watts has made major contributions to the successful development of the University's successful pharmacy education program.

In other Campbell news, the following new faculty members have been recently appointed: Russell C. Bowes, PhD, Assistant Professor of Pharmaceutical Sciences; Dawn M. Eberwein, PharmD, Assistant Professor of Pharmacy Practice (Reynolds Health Center, Winston-Salem); Sally A. Rodgers, PharmD, Assistant Professor of Pharmacy Practice (Wilson Community Health Center); Anita Taylor, PhD, Assistant Professor of Pharmaceutical Sciences; and Jeffrey B. Washam, PharmD, Assistant Professor of Pharmacy Practice (VA Medical Center, Durham).

The following new residents in pharmacy practice have been appointed: Sylvia Saint-Amand, PharmD (Primary Care/Managed Care); Cheryl Wiens, PharmD (Geriatrics); Michelle Long, PharmD (Campbell University Drug Information Center); Beth P. Mills, PharmD (Wilson Community Health Center); and Beatriz Luna, PharmD (Duke University Medical Center.)

The following new staff members have also been added: Jena T. Kelly, MBA, Administrative Assistant to Director of BS in Pharmaceutical Sciences Program and Sarah Simmons, BA Mass Communications, Director of Alumni Affairs and Placement.

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Patient Communication Made Easier for Pharmacists

by Jason Sharpe

Pharmaceutical care is the next generation of pharmacy practice, which goes beyond the traditional pharmacy service of filling prescriptions. The focus of care is the patient rather than the use of the drug, and communication between the patient and the pharmacist is one of the most important factors in pharmaceutical care. When there are problems in communication, patient compliance decreases and the patient's sense of satisfaction with the pharmacist is lessened. Communication is enhanced when the pharmacist is aware of the patient's general style of responding and communicating.

A new software program, known as Patient Communication Insights (PCI), has been developed to aid pharmacists in effectively communicating with their patients. The goal of PCI is to develop a quick and inexpensive method to assess behavioral characteristics that influence the patient's actions in a medical setting, thus enabling the health care team to communicate in the most effective manner to enhance efficiency, cost-effectiveness and patient satisfaction.

PCI is a testing instrument that identifies effective communication strategies based on the behavior style of the patient. The test utilizes a 3-5 minute written form filled out by the patient and scored via computer data entry. Patients must be able to read at a 6th grade level. (Tests are available in English or Spanish.) Data entry requires one minute of staff time. The PCI software program generates a one page PCI report describing the patient's behavioral style under stress conditions and identifies effective strategies to enhance communication for health care professionals.

Patient Communication Insights was validated with the Style Analysis testing instrument. Style Analysis is a well-established personality analysis instrument based on the works of Karl Jung and William Mouton Marsten. It differs from many other instruments that measure personality because behavior is studied based on emotional response to current environment and emotional response under stress.

The development of the Patient Communication Insights assessment instrument grew out of a need to have a short and inexpensive way to assess characteristics that influence the way a patient behaves in a medical setting. Recent changes in health care delivery and reimbursement have emphasized the necessity for efficient and cost-effective approaches to patient care. This emphasis has highlighted the need to be able to assess the patient quickly and be able to communicate with him/her in the most effective manner to enhance medical care and patient satisfaction.

The PCI development process was based on four criteria: 1.) the instrument must be short, easily administered and scored; 2.) the instrument must be based on a well-validated conceptualization of behavior; 3.) the information generated by the instrument must be seen as an accurate description of behavior; and 4.) the information generated by the report must be perceived as useful for medical practices.

The Style Analysis Instrument, a widely-used and well-validated assessment device used in personnel selection and management, was chosen as the source instrument for developing the PCI. The Style Analysis produces scores on four dimensions: D - Dominance, I - Interacting, S - Steadiness and C - Conformity. The nature and patterns of scores along these dimensions allows for the development of descriptions of behavior that have been found to predict a wide range of behaviors in a number of areas. The patient is asked to mark the word group that "best describes" him/her and the word group that "least describes" him/her. Each block contains word groups drawn from each dimension.

A sample of 100 individuals was administered the PCI as part of a study of interests and values. At the completion of all the inventories, each individual was given a copy of the PCI interpretive printout and asked to rate the accuracy of the report. The subjects were asked to rate the accuracy of the description on a 5-point scale from "extremely accurate" (5) to "not accurate at all" (1). The subjects were also asked to rate how useful they saw the statements on enhancing treatment compliance and trust on a 5-point scale from "extremely useful" (5) to "not useful at all" (1).

Ratings on the accuracy of the description were taken from 100 new patients in Colleyville, Texas, in the Family Practice Clinic, Baylor Hospital System. They revealed that 86 percent of the subjects rated the description as at least "very accurate," and only one subject rated the descriptions "not accurate at all."

Percentage of Ratings of Accuracy (n=100)

Extremely Accurate	=	56%
Very Accurate	=	30%
Somewhat Accurate	=	8%
Not Very Accurate	=	4%
Not Accurate At All	=	2%

Ratings on the usefulness of the information to the health care team were taken by 100 North Texas School of Medicine students. They revealed an even higher level of agreement. Eighty-nine percent (89%) of the subjects rated the information as at least "very useful" to the health care team in treating the patients.

Percentage of Rating of Usefulness (n=100)

Extremely Useful	=	58%
Very Useful	=	31%
Somewhat Useful	=	9%
Not Very Useful	=	2%
Not Very Useful At All	=	0%

NCPhA has agreed to co-market the PCI software program with HealthCare Insights. HCI is a division of the Hall Group, a multi-industry consulting firm with 25 years of experience assessing and training over 1.5 million individuals. Currently, more tests in a variety of pharmaceutical settings are being administered to determine how effective this software program will be in the pharmacy field. So far NCPhA has received very positive feedback from the pharmacists that are testing the PCI program. NCPhA is looking for more pharmacists to test PCI in their practice settings. If you are interested in obtaining a free trial version of the program please contact NCPhA at 1-800-852-7343. PCI is a Windows-based program and the software installation is self-explanatory. The pharmacist can use the report with the patient within a few minutes of installation.

If you want to judge for yourself how accurate and useful PCI is, turn to page 16, photocopy the page and fill out the survey for yourself. Fax it back to NCPhA at (919) 968-9430 for an analysis. Be sure to include a fax number so that we can return the evaluation to you as soon as possible.

Please complete the following PCI survey and fax to NCPhA at (919) 968-9430. Include a return fax number so that we can send back your evaluation form. Please mark on your survey if you would like to test the software and provide data for NCPhA.

Patient Communication Insights

In order to help us provide better health care, we would appreciate your completion of this ***Patient Communication Insights*** form.

First Name _____ Last Name _____ Male / Female Sex

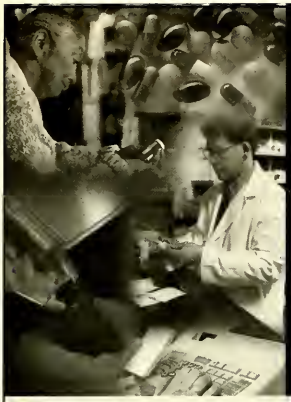
INSTRUCTIONS:

* **Rank each of the 4 words 1 to 4.**
* **Give the word that BEST describes you a 1.**
* **Give the word that SECOND best describes you a 2.**
* **Give the word that NEXT best describes you a 3.**
* **Give the word that LEAST best describes you a 4.**

_____ Charming _____ Helpful _____ Reserved _____ Competitive	_____ Argumentative _____ Convincing _____ Easy-going _____ Orderly
_____ Even-tempered _____ Unbeatable _____ Co-operative _____ Cheerful	_____ Optimistic _____ Neighborly _____ Vigorous _____ Organized
_____ Considerate _____ Playful _____ Precise _____ Self-reliant	_____ Logical _____ Outspoken _____ Adaptable _____ Persuasive
_____ Patient _____ Sociable _____ Cautious _____ Adventurous	_____ Modest _____ Perfectionistic _____ Strong-willed _____ Good mixer
_____ Moderate _____ Decisive _____ Agreeable _____ Talkative	_____ Generous _____ Daring _____ Good-natured _____ Structured
_____ Pioneering _____ Peaceful _____ Enthusiastic _____ Satisfied	_____ Content _____ Analytical _____ Popular _____ Bold

On behalf of your healthcare team, thank-you for taking a few moments to complete this ***Patient Communication Index!*** The ***Patient Communication Insights*** has been designed to help your healthcare team serve you further through more effective and efficient communication.

HealthCare Insights, 1995 A Division of The Hall Group



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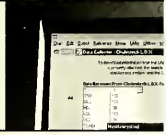

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Materia Medica

by Macary Barba Weck, PharmD Candidate,
UNC School of Pharmacy

Today, it is almost impossible to turn on the news, listen to the radio or read a newspaper without hearing or seeing a commentary on Viagra®. Marketed by Pfizer, Viagra® (sildenafil) is the only oral drug therapy indicated for the treatment of erectile dysfunction. Sildenafil is one of the fastest-selling drugs in history; some 20,000 prescriptions per day were written for the new drug in the third week after its launch date (1). Recent news has exposed health care providers to potential dangers involving the use of Viagra®. In order to fully comprehend this interaction, the physiologic processes involved with an erection, the specific mechanism of action of Viagra® and general product information must be understood.

An erection is the result of changes in vascular tone and blood flow in the erectile tissue of the penis. Recent research suggests that erection is mediated by acetylcholine-induced synthesis and release of a noncholinergic, nonadrenergic neurotransmitter from nerve endings and endothelial cells in the corpus cavernosum. This transmitter, nitrous oxide, activates the enzyme guanylate cyclase, which converts guanosine triphosphate (GTP) to cyclic guanosine monophosphate (cGMP) in smooth muscle cells (2). An increase in cGMP concentrations reduces intracellular calcium concentrations and triggers smooth muscle relaxation and blood flow into the corpora cavernosum, leading to an erection (3). In the corpora cavernosa, cGMP is inactivated by the enzyme phosphodiesterase type 5 (PDE5). Sildenafil is a selective inhibitor of PDE5 and, therefore, enhances the relaxant effect of nitrous oxide released in response to sexual stimulation by increasing cGMP concentrations. Since sildenafil does not have a direct relaxant effect on smooth muscle, sexual stimulation is required for an erection.

The recommended dose of sildenafil is 50 mg as needed approximately one hour before sexual activity (4). The dosage may be increased to 100 mg or decreased to 25 mg; however, the maximum dosing frequency is once per day, regardless of the dose. In the clinical studies conducted, side effects noted were mild to moderate. The most common side effect, headache, was noted by 16% of patients receiving sildenafil and 4% of patients receiving placebo. Flushing and dyspepsia were also noted by 10% and 7% of patients receiving sildenafil, respectively. Abnormal vision was reported in 3% of patients and involved a blue color tinge to the vision, although increased sensitivity to light and blurred vision also occurred (4). Some men taking higher doses of the drug lost the ability to distinguish between blue and green. The American Academy of Ophthalmology has therefore called for further studies of the drug's long-term effects and warned men with retinal eye conditions to take the drug "with caution" and to use the "lowest dose level possible" (1). Overall, however, the results of the studies were extremely promising and the public has jumped on the chance to improve their quality of life through the use of this therapy.

To many, Viagra® may sound like a wonder cure; however, some vital pieces of information regarding its use need to be included in patient counseling. Sildenafil is contraindicated in patients who are using organic nitrates or other nitrous oxide donors, such as nitroglycerin, isosorbide dinitrate or sodium nitroprusside (4). Sildenafil potentiates the hypotensive effects of nitrate products; therefore, concurrent use of these medications can dangerously lower blood pressure and lead to death. Although Viagra® is packaged with this warning, this danger may go unnoticed if not brought to the patient's attention. Additionally, other health risks with Viagra® are possible. Since sildenafil is metabolized primarily by CYP 450 isoenzyme 3A4, it can also be affected by drugs that inhibit or induce this enzyme. Cimetidine, a nonspecific inhibitor of 3A4, caused a 56% increase in plasma sildenafil concentrations when 800 mg doses were given with 50 mg sildenafil doses (4). Since OTC products are not typically part of pharmacy dispensing records, pharmacists should ask their patients about their use of nonprescription cimetidine and warn them of this possible interaction. Sildenafil systemic exposure after single 100 mg doses was increased by 182% by erythromycin, a specific inhibitor of CYP 3A4. Stronger inhibitors of 3A4 such as ketoconazole and itraconazole are expected to have even greater effects. Conversely, inducers of 3A4 such as rifampin are likely to decrease plasma concentrations of sildenafil. Patients should also be warned about the risk of additive hypotension or dizziness when sildenafil and alcohol are consumed simultaneously. Alcohol intake should be discouraged especially in large quantities, for excessive intake damages the nerves involved in erection (5).

As many as 30 million American men may be affected by erectile dysfunction (5). This disorder may even be underreported due to the embarrassment and reluctance of patients to acknowledge problems of a sexual nature (2). Recognizing the sensitive nature of this condition, pharmacists should provide private counseling and specific attention to the physical and psychological aspects of this disease. The pharmacist will need to obtain a comprehensive medication history, specifically noting the use of organic nitrates as well as drugs which are inhibitors or inducers of CYP 3A4. Misconceptions about Viagra® and its use may occur due to the extensive media coverage this drug has received. It is the responsibility of the pharmacist to disseminate the correct information about Viagra® to the patient so that he may avoid any life-threatening complications.

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Pharmacists in the News

• The American College of Clinical Pharmacy named **Donald W. Graff** of the University of North Carolina-Chapel Hill, as the Merck & Company Cardiovascular Research Fellowship recipient for 1998. **Angela M. Kashuba**, PharmD from the University of North Carolina-Chapel Hill, received the Bayer Pharmaceutical Community Infectious Diseases Research Award for her project titled "Characterizing Cytochrome P450 in HIV-1 Infected Women."

• **Harold Vann Day**, a six-term president and a member of the Board of Pharmacy for more than 36 years, was named the National Association of Boards of Pharmacy's (NABP) 1998-99 Honorary President during the Third Business Session at the Association's 94th Annual Meeting in Orlando. He is currently a pharmacist with CVS Pharmacy in Spruce Pines.

• The Watugua County Hunger Coalition (which now serves Ashe and Avery counties as well) has sponsored the first mobile pharmacy in the nation that gives access to free prescription medications. The **Country Roads Pharmacy** will serve those who cannot purchase prescription medications on a routine and regular bases although their health demands these medications. Often, their transportation is nonexistent or at best unreliable. All medications are given free of charge; most are physician samples and are supplied through the generosity of participating doctors. Pharmacists who staff the Country Roads Pharmacy are volunteers. For additional information, please fax The Hunger Coalition at (828) 262-0154.

• **Mr. Winfred A. King**, 72, of Mount Airy, died June 20, 1998. He was a graduate of the UNC School of Pharmacy. He was a practicing pharmacist with Lamm Drug and W.S. Wolfe Drug Co. for a total of 40 years.

• **Donald Floyd Brown**, 56, of Gastonia, died May 20, 1998, at his home. He was a 1967 graduate of UNC School of Pharmacy. He was the former owner of Caldwell Pharmacy and was employed as a pharmacist at Akers Pharmacy.

• **John Lee Jones, Jr.**, 72, of Canton, died May 25, 1998, at Haywood Regional Medical Center. He graduated from UNC with a degree in pharmacy in 1950. He was pharmacist, owner and operator of Thrif-Tee Drug in Canton which was formerly the Canton Drug Store.

• **William P. "Bill" Wells**, 78, of Durham, was laid to rest on Aug. 18, 1998. After serving in the Army during World War II, he obtained a pharmacy degree from UNC in 1953 and worked at Durham Drug Co., eventually becoming owner and operator.

• **Whit Moose** will be installed as president of NCPA, National Community Pharmacists Association, at their convention on Oct. 21, 1998.

News on Membership

Since June 1, 1998, over 130 new members have joined NCPhA. The most exciting news is that 86 of the new members are recent graduates from either Campbell University School of Pharmacy or the UNC School of Pharmacy. We hope that these young, enthusiastic pharmacists will become active participants and invigorate this Association and pharmacy as a whole.

Also, due to our membership drive in July, 32 new active members have joined, and we receive more forms every day. NCPhA celebrates this wonderful revival of the spirit of the organization, but we are not resting on our laurels. We vow to live up to the mission that we have set forth *to unite, serve and advance the profession of pharmacy.*

In the Next Issue:

1999 Pharmaceutical Directory

Testimony of David R. Work, Executive Director of N.C. Board of Pharmacy, Before the Subcommittee on Crime of the Committee on the Judiciary Thursday, August 6, 1998, 9:30 a.m.

If you think only bad people get in trouble with drug law violations, think again. Take, for example, a recent case in Florence, S.C., against six pharmacists and their employer. The civil complaint alleged more than 130 violations at $25,000 per charge for a total of over $3 million against these first offenders. The large majority of allegations were of a technical nature such as having a prescription dated in one place and not another or failure to complete a box on a federal form.

The core of the problem involved a carpet installer who did some work in a pharmacist's home. She did not realize that, in addition to his carpet skills, he was a con man with a history of several drug convictions in the Carolinas. When he learned that she was a pharmacist, he laid the groundwork for a scam to get drugs for his personal use.

He spoke of all the problems with his father's terminal illness so she saw nothing irregular when he brought a prescription to her store for a strong narcotic for his dad. After the first prescription was filled, a natural assumption of therapy to continue pain relief bypassed the scrutiny ordinarily applied to new prescriptions. Other pharmacists filled more of these prescriptions believing that they were meeting a legitimate need. When the pharmacists realized that the man's prescriptions were phony they turned him into authorities, and he is now in prison.

The Federal Drug Enforcement Administration (DEA) then aggressively took over the case and combined it with some technical violations in two other stores more than 100 miles away for an overwhelming number of charges and penalties into the millions of dollars. All this for conduct that may have been naive but never intentionally illegal with no profiteering and no diversion to the illicit market.

The pharmacist who reported the forgeries, identified the culprit and assisted in his apprehension was then charged with more offenses than the perpetrator. She faced 39 counts while he had 19 charges brought against him. One could not find a better example of the "unwarranted use of federal power" as recently described by Attorney General Janet Reno.

Now as a practical matter the defendants in the case can attempt to fight the government but they are not likely to win more than 130 in a row. Not to mention that in today's climate there is often a public presumption of some culpability with so many charges and even more so when drug offenses are involved. As you might imagine the pharmacist defendants felt avalanched when they received the court papers stating "The United States of America v. Jane Doe." Three of the six pharmacists in the case are women.

This is not the first time a case such as that one has occurred. In Raleigh, N.C., for example, a non-profit hospital paid $225,000 and a local chain drug store coughed up $325,000 to settle similar claims. While all of this is couched in proper legal terminology as a civil penalty, the solid citizen respondents in the case look on it as nothing less than extortion.

There are several reasons why this kind of complaint has not surfaced in the past. Laws and rules on drugs are so extensive that it is virtually impossible for a physician, pharmacist or nurse to effectively serve the public without a violation. I have a standing offer to all pharmacists that they can have one week to get their pharmacy in order and, if I can't find a violation in three minutes, I'll give them $5. Over the last twenty years nobody has accepted that offer. This reflects a realistic acceptance that there are so many drug laws that any health practitioner with a conscience who serves the public is probably a violator on a daily basis.

One such example occurred when a few days before Christmas last year letters arrived at 25 of the 30 pharmacies in Wichita County Texas at the instigation of the Drug Enforcement Administration (DEA). This greeting placed them on notice that penalties were due in amounts up to $400,000.

The violations our federal friends found were that prescriptions for controlled substances were written by resident physicians using a supervising doctor's DEA number with a suffix. Pharmacists at independent and chain pharmacies filled these prescriptions and all were charged with failure to conform to federal rules. Except for the chain stores, every owner said that paying up would put them out of business.

It is noteworthy that these same federal rules provide that the prescriber is responsible for proper prescribing and the pharmacist has a corresponding responsibility. When doctors have primary responsibility for prescribing but pharmacists, and not physicians, are charged with offenses committed by prescribers something is, as they say in the South, bad wrong.

It's important to note that none of these situations involved diversion of drugs to the resale market.

One could draw an analogy to basketball where the referee and other officials regulate the conduct of players. Those who violate the rules are charged with fouls, similar to pharmacist offenders getting tagged by enforcement authorities. Basketball has evolved from a time when any touching of an opponent was a foul to the current standard of no harm, no foul. As of today the DEA is calling $25,000 "touch fouls" on pharmacists. What's needed is a more reasonable positions such as "no harm, no foul" standard.

NORTH CAROLINA SOCIETY OF HEALTH-SYSTEM PHARMACISTS
NCSHP
Newsletter

Volume 21, Number 5 The bimonthly publication of the North Carolina Society of Health-System Pharmacists September/October 1998

Robotics: Changing pharmacy at PCMH

Pitt County Memorial Hospital (PCMH) has joined several other North Carolina hospitals who provide automated medication dispensing via robotics. Last year the Department of Pharmacy Services at PCMH piloted, then rolled out hospital-wide automated medication cart filling. Although many operational details had to be streamlined and occasional problems rectified, robotics have offered our department increased medication dispensing accuracy and personnel time savings for other professional activities.

Prior to obtaining robotics, medication cart fill for 663 beds would take five technicians approximately 15 hours and four pharmacists 14 hours to check and update. As with any human task, error in medication filling of the carts occurred. In an effort to reduce these errors and increase pharmacists' time to provide more pharmaceutical care activities, robotics was considered. After a thorough review of available vendors, ROBOT Rx® by Automated Healthcare was selected.

Our robot required a housing minimum of 135 sq. feet, necessitating renovation of existing space for robot placement. Several months were required for room renovation and robot set-up, including installation, prepacking products, staff education and development of procedures. Additional months were needed for piloting robotic cart fill and subsequent graduated replacement of centralized cart fill before hospital-wide cart fill began in November of last year.

Prior to robotics, it took four pharmacists a total of 14 hours to check medication carts. With robotic cart fill, it takes one pharmacist 1.5 hours daily to check the small manual cart fill and spot check the robot fill.

ROBOT Rx® operates on a track running between two walls of medications which are placed in plastic bags containing specific bar coding for the medication and placed on individual hangers. When a technician activates the cart filling process, medication bins with patient-specific identifiers are placed on a conveyor belt for the journey back to the robot. The pharmacy's computer system, Cerner, sends the robot a list of medication prescribed for the patient. The robot then moves up and down the track stopping at locations where the prescribed medications are stored, reads the bar codes on each bag of medication and slides it off the respective hanger. This process is repeated for each of the patient's medications. Then the robot arm takes all of the patient's medications and places them into the patient's medication bin at the end of the track. This process is repeated until all patients on each requested unit have their medication bins filled. A conveyor belt moves the filled bins back to the operating technician who loads the bins to a cart for delivery to the appropriate nursing unit. It takes the robot approximately six hours to fill medication bins for 663 beds, which is considerably less time than it previously took to manually fill the medication bins (i.e 15 hours).

Other functions the robot performs includes scanning for expired medications, printing out a restocking report, restocking medications and crediting patients for medications not administered. Much of the robot's technology

Continued on page 27

1998 Carolina Seminar Program

It's still not too late to register for the 1998 Annual Carolina Seminar to be held at the Holiday Inn Four Seasons in Greensboro. Wednesday, Oct. 7, 1998, and Thursday, Oct. 8, 1998, will be packed with educational sessions, administrative/clinical pearls and exhibit programs for pharmacists and pharmacy technicians. The focus of the morning session of the first day will be on managing patients with diabetes. New treatment approaches, issues involving patients with hypertension and lipid management of diabetics will be discussed. You will definitely want to be present for this detailed look at diabetes mellitus. After the morning session, more than 40 pharmaceutical and industrial companies will be presenting during the exhibits and luncheon. Once you have had an opportunity to mingle with the exhibitors and establish some new contacts, the afternoon program will feature a panel discussion entitled "Managed Care vs. Managed Cost: Where Are We Going?" The administrative/clinical pearls, evening exhibits, residency showcase and reception will round out this first day of programming.

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Dilemmas

by Leslie Mackowiak, MS

Fifteen years ago when I started this column as a way to share practical issues in managing hospital pharmacy, I can honestly say that I would never have expected to read, and never expected to write, a Dilemmas column which concerned itself with problems arising from the turn of the century. And certainly, I didn't expect a dilemma that involved computers and automated machines that are standard fare now in most of our hospitals and health-systems. Many of us worked using mainframe computer systems 15 years ago, but automated dispensing systems and computer based compounders were not yet on most of our horizons. And who was worrying about, or even thinking about THE YEAR 2000? Probably not many of us, and unfortunately, not many of the computer programmers in the world either. So here we are today in 1998 with the dilemma and panic of what to do, what to worry about, and when we settle down from the initial panic, the hard work of investigating and confirming what our departmental computer Y2K issues really are and what we need to do about them.

For those of you who do not keenly focus in on any and all sound bites or news items related the Year 2000, I will briefly bring you up to speed on the issue. Back in the olden days of the '70s when computer memory and storage was expensive, programmers saving any bit and bite possible did not use the first two digits of the century designation when referencing or storing dates. Later, as storage and memory became cheaper and we moved onto newer languages and relational database storage systems, in the rush to rewrite many applications, programmers not focusing on date issues but on the bigger need to rewrite applications continued using only the two century characters. Therefore, many applications which use dates in any processing or transaction will either assume that 00 is the year 1900, and of course, that's already passed, or assume that 00 is a holding place, as it is often set as the null value. In either case, the logical computer system will either calculate incorrectly or most likely just "blow up" because it does not know what to do.

The technical experts tell us that this is not a hard problem to solve because at least it's a known problem. But for those of you like me who manage pharmacy information systems, you will agree that often the hardest part is documenting the problem. Is it really a known problem? Can we trust that we know our systems and how they work and believe our vendors when they tell us that "It will be okay?"

So the first real dilemma is to identify all of the potential Year 2000 issues. We need to remember as we think through our systems that what computers do is collect, transact, process and store information. Then we need to look at each of these step by step. For example, we need to look at our collection methods and determine where dates are input or collected (most likely through an interface) for patient information or order information and then check with all of the vendors and systems that send, receive and use these dates to identify how it is used. Once we understand the issue points and validate issues with vendors and our IS departments, we then need to plan our correction or accept our applications will work. In either case, we must test our systems to the extent possible. Yes, our IS departments can and should help, but our systems are ours, and it will be our issue when the drugs are not correctly dispensed on Jan. 1, 2000. Another dilemma is that many of our systems do not have complete stand alone test environments wherein dates can be manipulated to test future dates. The other dilemma is the time to do all of this in our very busy, growing and changing work environments. But we must take the time now to investigate, test and plan because we know whether we have done this or not, the Year 2000 will come. I encourage everyone to share their experiences and begin now!

From the President

Share For Success

Steve Novak, MPA
President

We spent the last day of summer vacation at Looking Glass Falls in the Pisgah National Forest with my son, Nick, 13, and three of his friends. At the base of the 60-foot falls there is a natural pool where an older man was the only swimmer. He entertained the onlookers by diving off the rock face into the pool and disappearing in the dark water for minutes on end. Then he would eventually wave at us through the waterfall, letting us know he was behind it. If you looked carefully, you could see his silhouette. We had been there before but never knew you could swim behind the falls. The boys swam over but couldn't find access through the roaring water. After watching their frustrations, he finally shared with them the secret to the access - an underwater hole in the rocks that leads to the hidden area behind the falls. It's not apparent from above the surface. He offered to lead them through. We watched apprehensively as they disappeared under the water and were relieved to hear their laughter and see hands sticking out from behind the cascading falls. They eventually surfaced in the middle of the pool, lips blue from the cold, but exhilarated from their discovery.

Driving back that night, in a brief respite between battles for control of the music selection from the radio, I started thinking about the role the stranger played for the boys in discovery of the hidden passage. The passage was not apparent, hidden under the dark and cascading water. He provided both the knowledge and experience in successfully negotiating the way. The role of NCSHP in opening new passages for successful pharmacy practice for our members is analogous to the mentor role of the stranger. NCSHP provides a variety of opportunities for information exchange among our members: poster, pearl and educational sessions at our large meetings; formal and informal networking; the newsletter, the membership directory and web site; specific committees and special interest groups; and most recently, the Mentorship Program. The Mentorship Program is designed to share knowledge for success among more experienced practitioners and younger practitioners new to NCSHP. The program, started earlier this year by the membership committee, paired 18-20 new practitioners with volunteer mentors to share successful work place practices, knowledge and networking experiences at both NCSHP and ASHP meetings. NCSHP also has several programs in place to recognize both practitioners and practice sites for innovation and excellence. The Continuing Excellence Program recognizes practitioners who distinguish themselves through sustained service to the profession and public. The Innovative Practice Award recognizes practice sites for providing innovative programs and excellence in the profession.

NCSHP President Steve Novak, MPA

With the wide variety of programs and services available through NCSHP, the opportunities to contribute to our organization, the profession and society are significant. The key element in making it all work is your decision to actively participate in the process. By sharing your experience and knowledge as a mentor, meeting participant, committee member, innovative practitioner, etc., you start a chain of events that lead to other pharmacists' discovery and growth. They in turn can contribute their experience and knowledge to others. By making the decision to participate, you initiate a cascade of events that lead to excellence in the profession. Like the man at the waterfall, share what you know and watch what happens. The results are both fulfilling and exhilarating!

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NCSHP Newsletter is a bimonthly publication of the North Carolina Society of Health-System Pharmacists (NCSHP), a non-profit organization dedicated to the enhancement of health-systems pharmacy practice. Subscription to the newsletter is a benefit of membership in NCSHP.

NCSHP members are encouraged to share their views, concerns and ideas with their colleagues by contributing articles to The NCSHP Newsletter. Opinions expressed are those of the author and may not represent the views of NCSHP, its officers, Board of Directors or its membership. Copy deadlines are the 10th of the month prior to the month of the next issue to be published. (i.e. April 10th for the May/June Issue.)

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Clinical Consultant's Corner

Drug Interactions With Levothyroxine (Synthroid®, Various Generics)

by Alex McDonald, PharmD
UNC/Glaxo Wellcome Drug
Information Resident, April 1998

Levothyroxine is indicated as replacement or supplemental therapy in patients of any age or state (including pregnancy) with hypothyroidism.[1] Levothyroxine is also indicated as a pituitary thyroid stimulating hormone (TSH) suppressant in the treatment or prevention of various types of euthyroid goiters, including thyroid nodules, subacute or chronic lymphocytic thyroiditis (Hashimoto's), multinodular goiter and in conjunction with surgery and radioactive iodine therapy in the management of thyrotropin-dependent well-differentiated papillary or follicular carcinoma of the thyroid.

Recently, a report[2] of a drug interaction with calcium supplements occurred in three women with thyroid cancer receiving levothyroxine to suppress elevated levels of TSH. Calcium carbonate ($CaCO_3$, Tums®, Os-Cal®) was reported to reduce the efficacy of levothyroxine when the drugs were given concomitantly. One patient, with a baseline TSH level of 0.08 mU/L (reference: 0.5-4 mU/L) after taking levothyroxine, began taking $CaCO_3$ for osteoporosis prevention. Over five months, she began to experience fatigue and weight gain with a subsequent TSH level which had risen to 13.3 mU/L. After continuing levothyroxine for three weeks without calcium carbonate, her TSH level declined to 0.68 mU/L. In two other patients there was a loss of efficacy of levothyroxine when it was given with oyster shell calcium. The levothyroxine was then given while fasting in the morning and the calcium supplements were given after lunch and dinner. After separating the doses, TSH levels returned to normal.

Levothyroxine is reported to interact with a number of agents. (Visit *www.synthroid.com* for information table.) The levothyroxine-$CaCO_3$ interaction is newly reported and is likely to be widespread given that this combination may be used in a large number of patients, namely postmenopausal women. The administration of these medications should be separated by at least 4 hours. In addition, special attention should be given to patients receiving levothyroxine with $CaCO_3$ or any other drug.

The magnitude and relative clinical importance of drug interactions are likely to be patient-specific and may vary as a result of age, gender, race, other illnesses, dose of either agent, additional concomitant medications and timing of drug administration. Any agent that alters thyroid hormone synthesis, secretion, distribution, effect on target tissues, metabolism or elimination may alter the optimal therapeutic dose of levothyroxine.

Absorption

The following agents may bind and decrease absorption of levothyroxine from the gastrointestinal tract: aluminum hydroxide, cholestyramine resin, colestipol hydrochloride, ferrous sulfate, sodium polystyrene sulfonate, soybean flour (e.g., infant formula) and sucralfate.

Binding to serum proteins

The following agents may either inhibit levothyroxine binding to serum proteins or alter the concentrations of serum binding proteins: androgens and related anabolic hormones, asparaginase, clofibrate, estrogens and estrogen-containing compounds, 5-fluorouracil, furosemide, glucocorticoids, meclofenamic acid, mefenamic acid, methadone, perphenazine, phenylbutazone, phenytoin, salicylates and tamoxifen.

Thyroid physiology

The following agents may alter thyroid hormone or TSH levels, generally by effects on thyroid hormone synthesis, secretion, distribution, metabolism, hormone action, elimination or altered TSH secretion: aminoglutethimide, p-aminosalicylic acid, amiodarone, androgens and related anabolic hormones, complex anions (thiocyanate, perchlorate, pertechnetate), antithyroid drugs, ß-adrenergic blocking agents, carbamazepine, chloral hydrate, diazepam, dopamine and dopamine agonists, ethionamide, glucocorticoids, heparin, hepatic enzyme inducers, insulin, iodinated cholestographic agents, iodine-containing compounds, levodopa, lovastatin, lithium, 6-mercaptopurine, metoclopramide, mitotane, nitroprusside, phenobarbital, phenytoin, resorcinol, rifampin, somatostatin analogs, sulfonamides, sulfonylureas and thiazide diuretics.

References:

1. Synthroid® (levothyroxine) product information, Knoll Pharmaceuticals, 1998.

2. Schneyer CR. Calcium carbonate and reduction of levothyroxine efficacy. JAMA 1998;278(10):750

***Due to space constrictions, accompanying table could not be included. For a complete Levothyroxine Interaction Table, visit www.synthroid.com. ***

In Summary

Communications/Public Relations Committee Tackles Variety of Issues at Meeting

The Communications and Public Relations Committee of NCSHP met on Tuesday, Aug. 11, 1998, at noon at the Institute of Pharmacy in Chapel Hill to discuss a variety of topics. Several guests from NCPhA were also present for the discussion. The following report is the minutes for that meeting.

I. Update on NCSHP/NCPhA Web site Mark Ninno initiated the discussions by reviewing the current issues surrounding the NCSHP web site and the charges put forth by NCSHP to make improvements. While NCSHP has a functioning web site, obtaining timely and appropriate content is problematic. Shaun Kilgariff, of NC State University, provided an overview of a proposal to improve the technology side of the web site. The group discussed the role of the web site in obtaining new members and as a membership benefit. It was recognized that many pharmacists may not currently use the Internet in their daily practice, and it would be important to find out what features they would find useful enough to have them start using the Internet routinely. The issue of pharmaceutical industry financial support was also discussed, but it was felt that these monies should not be pursued until the time that the goal and content of the site is better established. It was felt that the issue of supplying uniform content to the web site was most important and should be addressed before new technologies are implemented. The group agreed on a stepped plan to improve the web site:

Step 1: Conduct a survey of pharmacists within North Carolina to determine what features would be most attractive to have available on the web site. This survey will be sent out in the November/December issue of the *Carolina Journal of Pharmacy*, distributed at the NCSHP Fall and Winter meetings, Annual Pharmacy Practice Seminar in Wilmington and distributed to current pharmacy residents and graduating pharmacy students. Results of this survey will be used to assess the content and technology needs of the web site.

Step 2: Present results of survey to the Boards of NCPhA and NCSHP to address financial, editorial and management needs associated with revising the NCSHP web site.

Step 3: Develop guidelines for the contribution of content from NCSHP/NCPhA committees and councils. This step will be implemented to assure that content is timely and consistently supplied to the manager of the web site.

After much discussion, the group felt that it was best to proceed with this project as a combined effort between NCSHP and NCPhA since the timeline was consistent with the timeline for the merger of the two organizations. Mark Ninno agreed to develop the survey tool in time for the Sept. 12, 1998, Annual Pharmacy Practice Seminar in Wilmington. A rough draft of the survey will be sent out to Committee members later this month for review and comment.

II. Pharmacy Week: The group reviewed the activities for the upcoming Pharmacy Week and Month. Jennifer Windley presented an overview of the materials used in past years and presented new ideas for 1998. Jennifer proposed to simplify the Pharmacy Week mailing packet by mailing a preprinted brown paper bag to promote "brown bag" day. This program can be utilized in community and hospital pharmacies alike. In addition, ASHP is making materials available for Health-Systems Pharmacists for pharmacy week activities. Vance Collins will have these materials available at the NCSHP Fall Meeting for anyone wanting them.

III. Update on the Adaptation of the FSHP Membership Recognition Program: Mark Ninno has completed the retype of the FSHP membership recognition letters. These letters will be forwarded to Cathy Jordan at NCSHP to be made available on file. The letters will be incorporated with new software soon to be available at NCPhA/NCSHP to facilitate the ease of distributing the letters.

IV. Update on the ASHP Grassroots Public Relations Campaign: Mark Ninno provided a brief update on NCSHP's activities with the ASHP Grassroots Public Relation Campaigns. Radio interviews throughout North Carolina have been conducted during the first two weeks in August. Mark Ninno has been acting as the state contact person for these interviews and has completed several to date. Vance Collins notified the Committee that ASHP would soon be sending out press releases and other material to promote health-systems pharmacists. Contact persons in the geographic areas identified at the June meeting still need to be identified. These persons will be responsible for providing press release materials to local television and radio stations. Vance and Mark will be seeking volunteers for these contact positions. ASHP has sent materials that will assist in making initial contacts with media outlets.

V. Health-System Pharmacy Awareness Day

Mark Ninno will be seeking a volunteer to act as the liaison with Campbell University to set up Health-System Pharmacy Awareness Day. Interested individuals should contact Mark.

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AWARD OPPORTUNITIES

NCSHP offers three awards to pharmacists to recognize personal contributions to our profession. There is no better time to distinguish your patients, your practice site and yourself for your efforts to promote pharmacy over the past year. Nominations are currently being accepted for the (1) Continuing Excellence Award, (2) Innovative Practice Award and (3) Pharmacy Awareness Award. Applications for each of these awards may be obtained by contacting the NCSHP Office at 919-933-6760. The deadline for receipt of completed applications is Dec. 15, 1998. We understand that the end of the year can be extremely hectic, so please budget some time now in your schedule to compile the necessary paperwork and submit your applications before the deadline. Below is a brief description of the three awards and some clarification regarding applications. For answers to additional questions, please contact the 1998 Chair of the Nominations and Award Committee, Tim Giddens, at 910-671-5176.

The purpose of the *Continuing Excellence Program* is "to recognize individuals in the area of institutional pharmacy practice in North Carolina who have distinguished themselves through sustained service to the profession and the public, and to promote an awareness of NCSHP and the profession of pharmacy among the public and other health professions." Active NCSHP members must submit documentation of involvement in each of three categories. Category I is for Continuing Education Programs, Category II is for Pharmacist-to-Pharmacist Interactions and Category III is for Pharmacist Interactions with Other Health Professionals and/or the public. Documentation is required for each of the three categories above. For Category I, copies of CE certificates are adequate. In the past, documentation for Categories II and III was lacking or incomplete. For these categories, copies of meeting announcements, minutes, agendas, letters of invitation, thank you notes, summary evaluations, outlines used, letters of appointment to a committee or task force, letters of recognition, other correspondence between you and the group with whom you are working, copies of abstracts published, newspaper articles or other publications can be submitted. Participation in an activity should not be considered a mandatory part of your position and must be related to your role as a pharmacist. Successful recipients will be notified by Jan. 15, 1999, and will be presented a Certificate of Continuing Excellence at an NCSHP meeting.

The *Innovative Practice Award* is designed "to recognize health system practice sites in North Carolina which have developed innovative programs and excelled in the profession, and to promote an awareness of NCSHP and the profession of pharmacy among the public and other health professions." Active NCSHP members can submit documentation of involvement in a program or project that is preferably patient-oriented. Examples of innovative programs may include: new clinical services, ambulatory care clinics, pharmaceutical care or clinical services that impact length of stay or cost of goods and services, patient teaching programs or significant formulary restrictions/therapeutic substitutions. The site can apply for different services but the same program cannot be considered for the award unless there have been new changes with documented outcomes. Innovative practice sites will be reviewed on each of the following criteria: objective of the program or project, innovation and relevance, methodology, outcome measurements and applicability of results. Small practice sites as well as large practice sites are encouraged to apply. Successful recipient sites will be notified by Jan. 15, 1999, and will be presented an Innovative Practice Award at an NCSHP meeting.

The purpose of the *Pharmacy Awareness Award* includes "recognizing practice sites in North Carolina which have promoted the public's knowledge and awareness regarding the role of pharmacy and pharmacy education during National Pharmacy Month." Practice sites with pharmacists who are active NCSHP members may apply. A brief description of the program, project, event or article is needed. Photos or other documentation of the program may also be included. All applicants will be evaluated on creativity, originality, targeted population and any measurable outcomes. The site with the winning idea will have their program promoted during Pharmacy Awareness Month next year.

For each award, the NCSHP President will send a letter of commendation to the chief administrator of each recipient site and news releases to local newspapers. Also, all winners will be announced in the *NCSHP Newsletter*.

Continued from page 21

relies on bar coding of medications. For those medications not available in bar coded packaging, a packager must manually prepare packaging with a bar code. In addition, certain medications such as bulk items which are not compatible with robotic handling must be filled manually by technicians, as was done in the past. It is advantageous to have the robot fill as many of the patient's medications as possible. A goal that we set was to have 85 percent of all patient's medications be filled by the robot. We have been able to accomplish and even exceed this, although it requires a great deal of effort by supervising pharmacists and technicians to insure that the appropriate medications are loaded into the robot.

One of the advantages of robotic cart fill is conservation of technician time, allowing for deployment or staff reductions. As mentioned previously, it required five technicians to manually fill all medication bins. With the robot, that number has been reduced to three technicians (repacker, restocker and one tech to operate the robot). In addition, there has been a reduction in pharmacist time required to check and update the patients' medication carts. Prior to robotics, it took four pharmacists a total of 14 hours to check the medication carts. With robotic cart fill, it takes one pharmacist 1.5 hours daily to check the small manual cart fill and spot check the robot fill. Another potential advantage of the ROBOT Rx® is the capability of dispensing first dose medications. At this time, PCMH is undecided on whether to use this particular robotic function.

Several disadvantages with the robot include the attendant noise associated with its pneumatic operating system. The machine produces a constant chorus of whirs, clicks and hisses as it completes its daily chores. ROBOT Rx® is not inexpensive; the purchase price including hardware, software and support fees approaches the one million dollar mark. Over the last year of operation, the robot has been "down" only a handful of times. However, each department must have a definite "down time" plan when this occurs to prevent compromising patient care services. At our hospital, cart filling is performed on third shift, potentially necessitating calling in additional staff for manual cart filling if the robot is non-functional.

In conclusion, our department's venture into the use of widespread dispensing technology has generally been positive, although the system has been in operation for only nine months. In using robotics, bar coding technology has been initiated into medication management and lays the foundation for further technology advances in medication administration such as the AccuScan® point of care system. Robotics have offered increased dispensing accuracy and personnel time savings. We hope to take the pharmacist and technician time saved and offer increased pharmaceutical care for patients at PCMH.

~Article provided by PCMH~

Calendar of Events

October 7-8, 1998
NCSHP Annual Carolina Seminar
Greensboro

November 14, 1998
Technician Certification Exam
Asheville, Charlotte, Durham, Fayetteville

December 6-10, 1998
ASHP Midyear Clinical Meeting
Las Vegas, NV

February 11-12, 1999
North Carolina Pharmacy Winter Meeting
Greensboro

May 20-23, 1999
NCPhA Convention
Atlantic Beach

June 6-10, 1999
ASHP Annual Meeting
Reno, NV

July 31-August 2, 1999
ASHP Home Care Meeting
Chicago, Ill

October 6-7, 1999
Annual Carolina Seminar
Greensboro

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PROFESSIONAL OPPORTUNITIES ABOUND

Continued from page 21

An update on low molecular weight heparins will begin the second day of the Seminar. Look for sessions discussing their inpatient and outpatient use, cardiology implications and risk stratification. After the exhibits and lunch, we will return with pharmacotherapy updates on quinolone antibiotics and HIV. These full two days can provide pharmacists with up to 10 contact hours of continuing education credit so make plans to attend this wonderful program now! To register, please contact the UNC School of Pharmacy at 919-966-1128.

Do you or someone you know deserve special recognition? Would you like to inform other pharmacists and technicians of an activity at your practice site?

If so, please send your information to the NCSHP office at:
PO Box 968
Chapel Hill NC 27514 or
NCSHP@mindspring.com.

We rely on our readers to keep us informed of our members' activities. Your help in locating future articles for the *NCSHP Newsletter* is greatly appreciated!

Pharm Tech Program

The Eighth Annual Fall Seminar *Contemporary Issues for the Pharmacy Technician* is right around the corner! Oct. 7, 1998, is quickly approaching and registration for this meeting is currently in progress. This will be the perfect opportunity to learn about various areas in pharmacy practice, meet fellow technicians and obtain 3.0 hours of continuing education credit. Katherine Trexler from Duke University Medical Center will begin the afternoon program with a session entitled "Total Parenteral Nutrition: What's it all About?" By the end of her talk, you should be able to identify the disease states for which total parenteral nutrition (TPN) is indicated and understand the proper techniques involved with TPN preparation. David Work, Executive Director of the NC Board of Pharmacy, will update the technicians on new Board rules and regulations. And finally, a lecture on "The Use of Botanicals in Healthcare" from UNC School of Pharmacy Clinical Assistant Professor June McDermott will familiarize you with eight herbal products commonly used by patients. Brochures have already been mailed out to NCSHP technician members and we encourage you to share this valuable information with other technicians in your workplace. For additional brochures or to register for this year's program, please contact the NCSHP office at 919-933-6760. We look forward to seeing you in Greensboro!

NCSHP Mentorship Program — Is it for You?

The NCSHP membership committee is very pleased to announce that the first fifteen mentors and mentees have been matched together for the NCSHP Mentorship Program. This program is designed to match new graduates, pharmacy students, technicians and pharmacists who may be new to the state with a member who has been involved with NCSHP in a leadership role. These leadership roles may include committee members and chairs, members of the board and current and past NCSHP presidents. One goal of the program is to stimulate enthusiasm for the association and profession. Another goal is to encourage future committee participation and other leadership type roles in the association. The mentors have been asked to contact their mentees at least four times a year and to introduce them to other pharmacists especially while attending state and national pharmacy meetings. The mentors may also provide guidance to the mentees about the association and pharmacy as a profession. If you are interested in participating in the Mentorship Program, either as a mentor or mentee, please contact the NCSHP office at 919-933-6760.

~LeAnne Kennedy,Chair~

By now you've noticed...

I hope that the new format for the *NCSHP Newsletter* is meeting expectations. It will, of course, take a couple of issues for me to straighten out all the bugs that seem to pop up when merging two separate publications. However, I wanted to thank the Communications/Public Relations committee, and especially Frances Gualtieri, for making the transition go as smoothly as possible. Also, I commend the contributing editors for their diligence in getting in great articles on time! It really makes my job much easier.

I wanted to make sure that all NCSHP members were aware of the changes in deadlines and submission policies. Any member is encouraged to submit relevant articles for publication. In general, articles should range from 400-600 words, though exceptions can be made. All articles are due by the 10th of the month preceding the issue month. For instance, Oct. 10th is the deadline for the November/December issue.

Articles can be submitted in a variety of ways. You can submit your article via e-mail (jenniferwindley@mindspring.com) as an attachment. You also can save it on a disk (PC or Mac). In both instances please save the article as a text or Word document file. Sorry, we do not use Word Perfect. Finally, if you cannot use either of these methods, feel free to fax or mail a hard copy of your article. Fax: (919) 968-9430 or mail to *Carolina Journal of Pharmacy*, Attn. NCSHP Newsletter, P.O. Box 151, Chapel Hill, N.C. 27516. Please include a brief statement about the author if possible, including place of work and degrees.

Thank you so much for your support. Please feel free to contact me with any questions.

— Jennifer Windley, CJP Editor

The Traumatized Family

by Deanna Mears Pandya, family counselor
The William J. Farley Center at Williamsburg Place

A family is a social system with structure, a set of cognitive schemes and a world view. It is where most of us learn how to have relationships and deal with life. We need each other. But for some, the family is under siege, and the home is a battleground. These families have an alcoholic and/or addict and co-alcoholic/addict in their midst. Their family life is a chaotic succession of crises. Family rituals, which give some order to chaos, are centered around the alcoholic/addict. Alcohol and other drug abuse is stressful to family members rendering them helpless and frustrated. The real victims are the children as they are powerless to change their situation and often internalize guilt and shame for the ongoing unpredictability.

The parents usually fill the roles of the alcoholic/addict and the co-alcoholic/addict. The alcoholic/addict is the under-functioning partner in the adult relationship, and the co-alcoholic/addict overcompensates allowing their partner to continue with the drug use. (Alcohol is a drug!) This symbiotic relationship is known as "enabling" because the co-alcoholic/addict prevents the addict from experiencing the full consequences of his/her behavior and enables him/her to put off dealing with the problem.

The behavior cycle of the enabler is to bounce back and forth between rescuer and persecutor. In the rescuing mode the enabler rewards drug use and when sober periods occur the enabler becomes the persecutor by issuing constant verbalizations and punitive actions of the alcoholic/addict's using behavior. The alcoholic/addict becomes the co-alcoholic's drug of choice. This enmeshed relationship of the primary caregivers prevents them from being emotionally available to provide the primary emotional needs of the children. Some of these primary emotional needs are clearer communication, appropriate boundaries and safety/security.

When children lack appropriate defined boundaries they are often victimized throughout their lifetime. Appropriate boundaries are taught through consistency in parental nurturing and guidance in allowing the child to experience his/her developmental stages. Inappropriate boundaries are taught via parentification of the "hero" child, expecting adult behavior and responsibility. It could also include the ignoring of the "lost" child, the blaming of the "scapegoat" child or the irritability with the "clown" child. These roles prevent individuation and good ego strength necessary for healthy relationships and life skills.

All communication carries a metacommunication. Metacommunication is a non-verbal message attached to the spoken words indicating how the receiver is expected to respond. Metacommunication includes voice inflection, body positioning, facial expressions and other vocal, kinesetic forms. In dysfunctional relationships, incongruent messages abound and the possibility for clarification of these messages does not exist. This creates a continuous mystification of the process occurring in the family relationships. This leaves children confused and fearful. Safety and security are compromised by the unpredictability, arguments, broken promises and some times violence.

Children are the real victims, and they suffer immensely because they have the least options for dealing with the craziness. When they are in their own developmental crises, they have no available parent to help them. The children are either hostile-dependent or hyper mature caretakers to the dependent, demanding parents. Their attempts to gain permission to be children vary from depressive periods of guilt, concern and helplessness or a secretive life of drugs and/or other life-threatening behavior.

Parents often minimize and deny the impact substance abuse has on their children. They forget that children wake up at night when there are arguments/fights, they overhear conversations during the day, and they are keen observers of their environment. From birth to age 12, the negative aspects of self that a child must overcome developmentally are shame, doubt, guilt and inferiority. The chances of a child being overcome by these negative aspects of self are great in a alcoholic family.

The entire family needs help, not just the alcoholic/addict. Options include therapy or Twelve-Step groups such as Al Anon, ACOA, Nar-Anon, CODA, Al-Atot or Al-Ateen. The real treatment of the family does not end with sobriety, it is only the beginning. If the alcoholic/addict never seeks recovery, the family stills needs to seek their own.

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Patient Counseling: Benign Prostatic Hyperplasia; Part 2: Medical Management

Gossel

Wuest

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Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph.,
PharmD.
Professor of Pharmacy Practice
University of Cincinnati
Cincinnati, Ohio

Goals. The goals of this two-part lesson are to discuss benign prostatic hyperplasia, and to present information useful in counseling patients.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. identify the causes and etiology of benign prostatic hyperplasia;
2. exhibit knowledge of the drug and non-drug treatment options, and methods to prevent benign prostatic hyperplasia;
3. show an understanding of the pharmacologic actions and adverse effects associated with drugs used to treat benign prostatic hyperplasia; and,
4. demonstrate an ability to counsel patients on prevention and treatment of the condition.

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Benign Prostatic Hyperplasia

Benign prostatic hyperplasia (BPH), enlargement of the prostate gland, is reported almost universally in older men. By age 50, about 25 percent of them will notice a decrease in the force of their urine stream. The incidence increases to approximately 50 percent by age 75, and 90 percent by age 80. One out of four males living past age 80 will require treatment for this disorder.

BPH is a progressive disease that is an example of true hyperplasia (increased cell number). The term *hypertrophy* (increased cell size) is inappropriate when describing BPH.

Pharmacologic Intervention

Pharmacologic management of BPH has increased in importance over the years since many patients prefer to avoid surgery and possible postsurgical complications. There is convincing evidence that pharmacologic intervention may control symptoms effectively in selected patients. It will be considered for males who do not want to undergo surgery, or who are poor surgical risks.

At present, there are two approved therapeutic interventions using pharmacologic agents. These include reduction of adrenergic tone in the bladder and prostate gland, and reduction of prostate gland size through inhibition of hormonal stimulation of its cells.

Adrenergic Blockade

Smooth muscle comprises a significant portion of prostatic stroma (supportive cellular framework). The ratio of stroma to epithelium increases by 2.5 times in BPH compared to normal tissue.

There is a high density of alpha-1 adrenergic receptors in the prostate gland and bladder neck. Stimulation initiates smooth muscle contractions in a hyperplastic prostate gland. It is therapeutically sound to treat symptoms of BPH by reducing the sensitivity of these receptors. Blocking them relaxes the muscles of the prostate gland, thus decreasing their tone and increasing urine flow rates. It is believed that the concentration of alpha-1 adrenergic receptors is proportional to the muscle mass within hyperplastic prostate tissue. The greater the muscle mass the greater the number of receptors, and the more responsive the tissue may be to alpha-1 adrenergic blockade.

BPH reflects an increase in stroma, connective tissue, and glandular epithelium. Alpha-1 adrenergic blockade affects only the smooth muscle component of these tissues so it only partially relieves urinary obstruction. While alpha-1 adrenergic blocker drugs relieve bladder outlet obstruction, they do not reduce prostate size or inhibit testosterone synthesis.

Phenoxybenzamine (Dibenzy-line) was the first agent used to treat BPH. It produces long-lasting blockade of both alpha-1 and alpha-2 adrenergic receptors. Although it improved urine flow rates, it also caused significant adverse effects such as vertigo and orthostatic hypotension. This drug never made an impact in the treatment of BPH.

Treatment with alpha-1 adrenergic blockers is particularly suited for elderly hypertensive men, since both conditions are characteristic of aging. The choice of drug is determined by the incidence of adverse effects and elimination half-lives, which determine the dosage schedule. All three agents have long biological half-lives, permitting single daily dosing.

Adverse effects are similar for all alpha-1 adrenergic blockers. Dizziness, headache, fatigue and orthostatic hypotension have been reported. The latter can be minimized by administering doses at bedtime. It has been suggested that blood pressure be monitored routinely during therapy, al-

though the incidence of drug-related hypotension is similar in normotensive and hypertensive patients.

It remains to be determined whether alpha-1 adrenergic blockers are effective for long-term control of BPH. They offer an alternative to surgery for patients with mild to moderate symptoms who do not have an absolute indication for surgery.

Three drugs with specific peripheral alpha-1 adrenergic blocking activity are currently indicated for treating BPH. Their actions are similar pharmacodynamically. Differences are due mainly to pharmacokinetic considerations.

Terazosin (Hytrin) was the first to receive FDA approval for BPH. It is also the most extensively studied of the group. A long-acting, selective alpha-1 blocker, terazosin produces significant improvement in obstructive symptoms and urine flow rates. In one clinical trial, there was improvement in obstructive symptoms in 67 percent of patients, in irritative symptoms 35 percent, and in all symptoms 54 percent.

Doxazosin (Cardura) was indicated initially for treating hypertension. When information became available that alpha-1 adrenergic blockers might be helpful in alleviating symptoms of BPH, its manufacturer conducted the necessary clinical trials to add this indication. The drug was shown to provide rapid and long lasting improvement in symptoms and urine flow rate in up to 71 percent of patients.

Tamsulosin (Flomax) is the newest alpha-1 adrenergic blocker with selective binding specificity for receptors in the genitourinary system. It is not believed to have significant binding affinity for alpha adrenergic receptors in the cardiovascular system.

Prazosin (Minipress), although useful in treatment of hypertension, is not indicated for BPH. This is due more to a marketing decision rather than lack of efficacy.

Hormonal Therapy

The principle hormone that regulates both normal and hyperplastic growth of prostatic tissue is dihydrotestosterone (DHT), the active metabolite of testosterone. The testes produce testosterone. Synthesis is controlled directly by secretion of gonadotropin-releasing hormone (GnRH), also referred to as luteinizing hormone-releasing hormone (LHRH). GnRH stimulates luteinizing hormone (LH) release which, in turn, binds to receptors in the Leydig cells of the testes where it increases testosterone synthesis. Conversion of testosterone to DHT is catalyzed by the enzyme 5-alpha-reductase.

Hormonal therapy is effective, although clinical response may be less than desired because only glandular epithelium is amenable to hormonal treatment. This represents approximately 30 percent of the prostate gland volume in BPH. If hormonal therapy is discontinued, the gland will enlarge to its former size. Patient acceptance may be limited by untoward adverse effects.

Luteinizing Hormone-Releasing Hormone. Gonadotropin-releasing hormone analogues or luteinizing hormone-releasing hormone analogues, such as leuprolide (Lupron) and goserelin (Zoladex), inhibit the release of gonadotropins from the pituitary. This reduces production of testosterone. DHT and 5-alpha-reductase concentrations are also decreased.

Between 50 and 70 percent of males on these drugs report loss of libido (sex drive). In spite of a 95 percent reduction in prostate size in six months, only one-third of males in clinical trials report significant lowering of BPH symptoms.

Anti-androgen Therapy. Anti-androgen agents antagonize the action of DHT at its target tissue by competing for its binding sites. Anti-androgens reduce prostatic volume, but do not inhibit testosterone production. This maintains sexual potency, but adverse effects such as nausea, diarrhea, and gynecomastia (breast enlargement in males) are common and can be bothersome.

Flutamide (Eulexin) prohibits DHT from binding to receptors in the prostate, initiating increased LH and serum testosterone levels. In one clinical trial, prostatic volume was reduced 23 percent in the treatment group, compared to no change with placebo. More than one-half of the patients reported breast pain or gynecomastia, and nearly as many experienced gastrointestinal side effects. Flutamide, indicated for treating prostate cancer, is not approved at this time for treatment of BPH.

Progestational anti-androgens, such as megestrol acetate (Megace) and cyproterone acetate (Andro-cur), also block DHT receptors and inhibit LH centrally. The LH inhibition reduces testosterone production which, in turn, reduces serum testosterone concentrations. This can lead to decreased libido and impotence.

5-Alpha-Reductase Inhibitors. Finasteride (Proscar) is the first, and currently the only, 5-alpha-reductase inhibitor approved for treatment of BPH. Finasteride results in a 20 to 25 percent reduction in prostate size that will be maintained during therapy. It offers significant advancement in hormonal regulation of this disorder for males with moderate symptoms.

When the enzyme 5-alpha-reductase is inhibited, testosterone conversion to DHT is blocked. Since DHT is the most potent prostatic androgen and the provoker of hyperplastic cell growth, inhibiting it removes the source of glandular stimulation. By inhibiting only DHT without reducing testosterone blood levels, adverse effects associated with generalized androgen blockade are minimized. Intracellular testosterone concentration is actually increased, thus sexual dysfunction is minimized.

The results of long-term finasteride therapy on prostate size are summarized in the "Proscar Long-term Efficacy and Safety Study (PLESS)." A total of 3,016 males were randomized into a treatment (1,513 subjects) or placebo (1,503 subjects) group. Finasteride was administered at a daily dose of 5mg over four years. The primary endpoint was improvement of symptoms. Secondary endpoints included reduction in BPH-related surgery rates and acute urinary retention. Tertiary endpoints were peak urine flow rates and changes in prostate volume.

Over the period of the study, 152 patients (10.1 percent) in the placebo group versus 98 (6.5 percent) in the finasteride group underwent surgery for BPH. Overall, there was a 57 percent decrease in acute urinary retention rates in patients treated with finasteride. Risk reduction started as early as four months in some patients.

Adverse effects reported in clinical trials to date have been related primarily to sexual activity. These include decreased libido and ejaculate volume, and impotence. Each is reported in fewer than four percent of subjects.

Because of potential risk to a male fetus from absorbed drug causing abnormalities in their external genitalia, pregnant and sexually active females who could become pregnant should avoid exposure to crushed finasteride tablets. They should also avoid contact with semen of patients taking finasteride.

To date, no significant drug interactions have been identified in clinical trials. Finasteride is metabolized extensively in the liver, so its potential for interaction with the cytochrome P450 enzyme system should at least be considered. The drug is also highly bound to plasma protein.

Finasteride decreases serum concentration of prostate specific antigen (PSA). This must be taken into account when testing for prostate cancer. Moreover, PSA levels that increase in a patient taking finasteride may indicate noncompliance or a malignancy.

What About Saw Palmetto?

For nearly a century, saw palmetto has been touted for the management of genitourinary problems, increasing the production of sperm, increasing sexual performance, and increasing breast size. It was included in the *National Formulary* at one time as a mild diuretic and treatment for prostatic enlargement. When the capacity of science to study drug activity reliably improved in the early-1900s, the therapeutic value of saw palmetto berry tea came under question and it was eliminated from the official compendium.

About 40 years ago, scientists discovered that dried saw palmetto berries contained sitosterols which had estrogenic activity. Since then, it has been shown that an extract of the berries has antiandrogenic activity through a direct action on estrogen receptors, by inhibition of 5-alpha-reductase, and by inhibition of DHT's ability to bind with its receptor sites.

So what about saw palmetto? While there is no absolute proof that it is effective in alleviating symptoms of BPH, there are many men who state that it works for them and physicians who believe in its use for mild cases. It has not been shown to reduce the size of the prostate gland as Proscar does. To its benefit, saw palmetto has not been reported to cause significant adverse effects. Headache is the most common complaint reported. Therefore, one might argue that patients with moderate to severe symptoms from BPH would be candidates for alpha-1 adrenergic blockers, finasteride or surgical reduction of the prostate gland. Men with early-onset, mild symptoms might be candidates for the use of saw palmetto, preferably under their physician's supervision.

Counseling Patients on BPH

Because of its prevalence in older males, it is probable that pharmacists will encounter patients with BPH frequently and this number will increase in the future as life expectancy increases and the population continues to age. Patients may seek advice prior to diagnosis and drug therapy. A few well directed questions can determine whether symptoms have occurred recently or are chronic, if they are mild or severe, and if the patient is currently under a physician's care for the condition. Responses will assist in making the proper recommendation to the patient. Some elderly males may be reluctant to discuss difficulties with urination, so they may need to be encouraged to relate their symptoms.

Symptoms of BPH can be relieved with therapeutic intervention. Therapy will not modify underlying pathologic changes. Males experiencing BPH usually seek medical assistance only when symptoms cause significant discomfort or their quality of life is affected adversely. Generally, males are more hesitant to seek medical advice than women, particularly for a condition which may be embarrassing to discuss. Often times, a spouse convinces them to do so.

Table 1
Patient Counseling Tips for Alpha-1 Adrenergic Blockers

- Cardura, Flomax and Hytrin are used to treat enlarged prostate (benign prostatic hyperplasia). Cardura and Hytrin are also used to treat high blood pressure.
- The manufacturers of Cardura and Hytrin state that doses can be taken with or without food. The manufacturer of Flomax advises that the dose be taken 1/2 hour after the same meal every day.
- Some patients have experienced lightheadedness while taking this medicine. If this occurs, it is best to sit or lie down at the first signs and avoid sudden changes in posture. Be careful going up and down stairs. Sometimes, this problem can be alleviated by taking the medication in the evening.
- This medicine may cause you to be drowsy the first few days you take it or when your doctor increases the amount you are taking. If it does, be careful driving or performing hazardous tasks. Alcoholic beverages can increase the drowsiness effect.
- It is best to take this medicine as instructed at approximately the same time every day. DO NOT skip a dose or stop taking the medicine without asking your doctor. Continue to take it as long as your doctor tells you, even if you are feeling well.
- Some OTC medicines can make urinating even more difficult. These include antihistamines and decongestants in cough/cold and hay fever remedies, sleep aids or diet medications. It is best to ask your doctor if it is okay to use these products on your own.

Patients with symptoms of BPH should avoid OTC products that have anticholinergic and/or sympathomimetic action. Such products include cough and cold remedies (antihistamines, decongestants), OTC appetite suppressants, sleep aids, and hay fever products. These can exacerbate urinary retention, and precipitate acute urinary retention in patients whose symptoms are already severe.

Retraining in urinary habits, such as allowing several uninterrupted minutes to urinate, may achieve more complete bladder emptying. The dosage of diuretics should be lowered as much as possible and be given as a single daily dose early in the day. Fluid intake, including beverages with diuretic

activity such as alcohol, coffee, tea and colas, should be restricted in the evening to reduce nocturia.

It is important for all males to receive regular prostate examinations after age 50. The incidence of prostate cancer increases after this age. While there is no correlation between BPH and prostate cancer, early symptoms of prostate cancer mimic those of BPH so it is easy for men to assume that cancer symptoms are a natural part of growing older (i.e., BPH). Prostate cancer that is detected and treated in its early stage is curable.

Summary

BPH will afflict most males to some degree as they age. Proper treatment requires an accurate diagnosis.

Drug therapy is suited for males who are poor surgical risks or who do not wish to undergo surgery. Drugs that block alpha-1 receptors and/or 5-alpha-reductase inhibitors are most effective in treating BPH, and they offer the best medical options. Tables 1 and 2 contain specific information which can be used when counseling patients taking these drugs.

Table 2
Patient Counseling Tips for Finasteride

- Proscar is used to treat enlarged prostate, a condition referred to as benign prostatic hyperplasia (BPH).
- This medicine should be taken with a glass of water and it can be taken with or without food.
- For proper control of your condition, it is best to take this medicine as instructed at approximately the same time every day. DO NOT skip a dose or stop taking the medicine without asking your doctor.
- It may take at least six months of treatment to determine if you will respond to this medicine.
- The amount of ejaculate may be decreased during treatment with this medication. This decrease does not interfere with normal sexual function.
- Some OTC medicines can make urinating even more difficult. These include antihistamines and decongestants in cough/cold and hay fever remedies, sleep aids or diet medications. It is best to ask your doctor if it is okay to use these products on your own.
- Females who are pregnant or who may become pregnant should not handle crushed tablets of this medicine because of the potential risk to a male fetus.

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Continuing Education Quiz

Patient Counseling: Benign Prostatic Hyperplasia; Part 2: Medical Management

1. The supportive cellular framework of the prostate gland is called the:
   a. detrusor.
   b. stroma.
   c. trigone.
   d. ureter.

2. All of the following alpha-1 adrenergic blockers are indicated for treating BPH EXCEPT:
   a. doxazosin.
   b. prazosin.
   c. tamsulosin.
   d. terazosin.

3. The principle hormone that regulates both normal and hyperplastic growth of prostate tissue is:
   a. deoxycorticosterone.
   b. dihydrotestosterone.
   c. medroxyprogesterone.
   d. methylprednisolone.

4. Patients with symptoms of BPH should avoid OTC products containing:
   a. antacids and/or calcium supplements.
   b. caffeine and/or ammonium chloride.
   c. aspirin and/or acetaminophen.
   d. decongestants and/or antihistamines.

5. The reason patients with BPH should avoid the products referred to in question #4 is because they:
   a. worsen urinary retention.
   b. increase bleeding tendencies.
   c. have an antidiuretic effect.
   d. interfere with electrolyte balance.

6. Alpha-1 adrenergic blockade is effective in BPH because it:
   a. diminishes the size of the prostate gland.
   b. inhibits testosterone synthesis.
   c. relieves bladder outlet obstruction.
   d. decreases renal blood flow.

7. Pregnant or sexually active females who could become pregnant should avoid exposure to crushed finasteride tablets and semen of patients taking finasteride because of the potential for drug-induced:
   a. abnormalities with male fetuses.
   b. breast cancer.
   c. abortifacient activity.
   d. photosensitivity reactions.

8. Finasteride reduces the size of the prostate gland by inhibiting:
   a. cytochrome P450.
   b. glucose-6-phosphate dehydrogenase.
   c. phosphodiesterase.
   d. 5-alpha-reductase.

9. By inhibiting the enzyme referred to in question #8, finasteride:
   a. increases atrophy of the testes.
   b. causes generalized androgenic blockade.
   c. removes the source of glandular stimulation of the prostate.
   d. decreases testosterone concentration throughout the body.

10. Stimulation of the alpha-1 adrenergic receptors in the prostate gland:
   a. initiates smooth muscle contractions.
   b. terminates smooth muscle contractions.

Complete and mail entire page with $7 check. Check must accompany test. Mail to: *Carolina Journal of Pharmacy* CE, P.O. Box 151, Chapel Hill, NC 27514. A continuing education certificate for 1.5 hour credit (.15 CEU) will be mailed to you. Please print clearly using, blue or black ink, or type. You must score 70% or more to pass. If you fail the first time, you may take one retest at no charge. Test must be submitted within one calendar year of the test date. This is a member service. Non-member tests will not be graded nor CPE credit hours given.

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Brown Bag It for Pharmacy Week

Tired of receiving hundreds of sheets of paper on terrific programs only to realize that you have no time to read through the information, much less implement anything? The NCPhA and NCSHP committees responsible for planning Pharmacy Week in North Carolina on Oct. 18-24, 1998, understand your dilemma. So this year in our state for Pharmacy Week, instead of receiving a thick envelope full of paper, you can expect something a little different. A lunch bag.

The committees want to make implementing a program easy and applicable for all pharmacists, whether in a community setting or a hospital. The hope is that the easier the program is, the more likely pharmacists are to carry it through. Since the theme for this year's Pharmacy Week is "Communicate to Stay Healthy - Talk to your Pharmacist," the committees thought that a program to encourage communication with patients would be ideal. Thus, the Brown Bag plan.

Soon, you should be receiving a "brown bag" in the mail. Inside will be three sheets of paper that will explain all you need to know to put together a patient friendly drug review or Brown Bag day. Simply write in the appropriate spaces on the bag a convenient day and time for you to hold consultations and place it in a visible area for your patients to see. (By the cash register or in your hospital cafeteria are good places.) Encourage your patients to bag up all of their prescription and OTC drugs, (any kind of bag will do!), and bring them in for review. Included in your mailing will be a Drug Review sheet for you to photocopy and go through with each patient. If you don't have traditional returning patients, it's easy to plan this same program for co-workers in hospitals or clinics. A helpful hint sheet for putting together a successful Brown Bag program in a variety of settings will also be included in your mailing. Finally, if you prefer to use other items, such as posters, buttons, balloons or advertisements, an order sheet for APhA materials will be included in the mailing as well. Call APhA at 1-800-822-1923 (8:30 a.m. to 5:30 p.m. CST) to order these special items.

Availability is one of greatest advantages pharmacy has to offer patients. We hope to see lots patients bringing brown bags full of medicines into pharmacy stores and hospitals all over North Carolina during Oct. 18-24. Take a stand and promote your profession this year by being an active participant in Pharmacy Week 1998.

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What is a Customer?

1. The customer is the most important person here.
2. The customer is not someone to argue with.
3. The customer is not an interruption of our work but the purpose of it.
4. The customer honors us when he or she calls.
5. The customer is part of our business and not an outsider — they are our guests.
6. The customer is not a cold statistic — he and she are flesh and blood, human beings with feeling and emotions like ours.
7. The customer is not dependent on us — we're dependent on the customer.
8. The customer who asks for a special service is providing us with an opportunity to show how good we are.
9. The customer is deserving of the most courteous and attentive treatment we can give.
10. The customer who is treated poorly may never come into our department again, and we know what that means to our public image.

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Please see brief summary of prescribing information on adjacent page

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Brief Summary (for full prescribing information see package circular)

SYNTHROID®
(levothyroxine sodium, USP)

SYNTHROID Tablets – for oral administration
SYNTHROID Injection – for parenteral administration

CONTRAINDICATIONS SYNTHROID is contraindicated in patients with untreated thyrotoxicosis of any etiology or an apparent hypersensitivity to thyroid hormones or any of the inactive product constituents. (The 50 mcg tablet is formulated without color additives for patients who are sensitive to dyes.) There is no well-documented evidence of true allergic or idiosyncratic reactions to thyroid hormone. SYNTHROID is also contraindicated in the patients with uncorrected adrenal insufficiency, as thyroid hormones increase tissue demands for adrenocortical hormones and may thereby precipitate acute adrenal crisis (see **PRECAUTIONS**).

WARNINGS Thyroid hormones, either alone or together with other therapeutic agents, should not be used for the treatment of obesity. In euthyroid patients, doses within the range of daily hormonal requirements are ineffective for weight reduction. Larger doses may produce serious or even life threatening manifestations of toxicity, particularly when given in association with sympathomimetic amines such as those used for their anorectic effects.

The use of SYNTHROID in the treatment of obesity, either alone or in combination with other drugs, is unjustified. The use of SYNTHROID is also unjustified in the treatment of male or female infertility unless this condition is associated with hypothyroidism.

PRECAUTIONS General SYNTHROID should be used with caution in patients with cardiovascular disorders, including angina, coronary artery disease, and hypertension, and in the elderly who have a greater likelihood of occult cardiac disease. Concomitant administration of thyroid hormone and sympathomimetic agents to patients with coronary artery disease may increase the risk of coronary insufficiency.

Use of SYNTHROID in patients with concomitant diabetes mellitus, diabetes insipidus or adrenal cortical insufficiency may aggravate the intensity of their symptoms. Appropriate adjustments of the various therapeutic measures directed at these concomitant endocrine diseases may therefore be required. Treatment of myxedema coma may require simultaneous administration of glucocorticoids (see **DOSAGE AND ADMINISTRATION**).

T_4 enhances the response to anticoagulant therapy. Prothrombin time should be closely monitored in patients taking both SYNTHROID and oral anticoagulants, and the dosage of anticoagulant adjusted accordingly.

Seizures have been reported rarely in association with the initiation of levothyroxine sodium therapy, and may be related to the effect of thyroid hormone on seizure threshold.

Lithium blocks the TSH-mediated release of T_4 and T_3. Thyroid function should therefore be carefully monitored during lithium initiation, stabilization, and maintenance. If hypothyroidism occurs during lithium treatment, a higher than usual SYNTHROID dose may be required.

Laboratory Tests Treatment of patients with SYNTHROID requires periodic assessment of adequacy of titration by appropriate laboratory tests and clinical evaluation. Selection of appropriate tests for the diagnosis and management of thyroid disorders depends on patient variables such as presenting signs and symptoms, pregnancy, and concomitant medications. A combination of sensitive TSH assay and free T_4 estimate (free T_4, free T_4 index) are recommended to confirm a diagnosis of thyroid disease. Normal ranges for these parameters are age-specific in newborns and younger children.

TSH alone or initially may be useful for thyroid disease screening and for monitoring therapy for primary hypothyroidism as a linear inverse correlation exists between serum TSH and free T_4. Measurement of total serum T_4 and T_3, resin T_3 uptake, and free T_3 concentrations may also be useful. Antithyroid microsomal antibodies are an indicator of autoimmune thyroid disease. The presence of positive microsomal antibodies in an euthyroid patient is a major risk factor for the future development of hypothyroidism. An elevated serum TSH in the presence of a normal T_4 may indicate subclinical hypothyroidism. Intracellular resistance to thyroid hormone is quite rare, and is suggested by clinical signs and symptoms of hypothyroidism in the presence of high serum T_4 levels. Adequacy of SYNTHROID therapy for hypothyroidism of pituitary or hypothalamic origin should be assessed by measuring free T_4, which should be maintained in the upper half of the normal range. Measurement of TSH is not a reliable indicator of response to therapy for this condition. Adequacy of SYNTHROID therapy for congenital and acquired pediatric hypothyroidism should be assessed by measuring serum total T_4 or free T_4, which should be maintained in the upper half of the normal range. In congenital hypothyroidism, normalization of serum TSH levels may lag behind normalization of serum T_4 levels by 2 to 3 months or longer. In rare patients serum TSH remains relatively elevated despite clinical euthyroidism and age-specific normal levels of T_4 or free T_4.

Drug Interactions The magnitude and relative clinical importance of the effects noted below are likely to be patient-specific and may vary by such factors as age, gender, race, intercurrent illnesses, dose of either agent, additional concomitant medications, and timing of drug administration. Any agent that alters thyroid hormone synthesis, secretion, distribution, effect on target tissues, metabolism, or elimination may alter the optimal therapeutic dose of SYNTHROID.

Adrenocorticoids–Metabolic clearance of adrenocorticoids is decreased in hypothyroid patients and increased in hyperthyroid patients, and may therefore change with changing thyroid status.

Amiodarone–Amiodarone therapy alone can cause hypothyroidism or hyperthyroidism.

Anticoagulants (oral)–The hypoprothrombinemic effect of anticoagulants may be potentiated, apparently by increased catabolism of vitamin K-dependent clotting factors.

Antidiabetic agents (insulin, sulfonylureas)–Requirements for insulin or oral antidiabetic agents may be reduced in hypothyroid patients with diabetes mellitus, and may subsequently increase with the initiation of thyroid hormone replacement therapy.

β-adrenergic blocking agents–Actions of some beta-blocking agents may be impaired when hypothyroid patients become euthyroid.

Cytokines (interferon, interleukin)–Cytokines have been reported to induce both hyperthyroidism and hypothyroidism.

Digitalis glycosides–Therapeutic effects of digitalis glycosides may be reduced. Serum digitalis levels may be decreased in hyperthyroidism or when a hypothyroid patient becomes euthyroid.

Ketamine–Marked hypertension and tachycardia have been reported in association with concomitant administration of levothyroxine sodium and ketamine.

Maprotiline–Risk of cardiac arrhythmias may increase.

Sodium iodide (^{123}I and ^{131}I), sodium pertechnetate Tc99m–Uptake of radiolabeled ions may be decreased.

Somatrem/somatropin—Excessive concurrent use of thyroid hormone may accelerate epiphyseal closure. Untreated hypothyroidism may interfere with the growth response to somatrem or somatropin.

Theophylline—Theophylline clearance may decrease in hypothyroid patients and return toward normal when a euthyroid state is achieved.

Tricyclic antidepressants—Concurrent use may increase the therapeutic and toxic effects of both drugs, possibly due to increased catecholamine sensitivity. Onset of action of tricyclics may be accelerated.

Sympathomimetic agents—Possible increased risk of coronary insufficiency in patients with coronary artery disease.

Laboratory Test Interactions A number of drugs or moieties are known to alter serum levels of TSH, T_4 and T_3 and may thereby influence the interpretation of laboratory tests of thyroid function (see **Drug Interactions**).

1. Changes in TBG concentration should be taken into consideration when interpreting T_4 and T_3 values. Drugs such as estrogens and estrogen-containing oral contraceptives increase TBG concentrations. TBG concentrations may also be increased during pregnancy and in infectious hepatitis. Decreases in TBG concentrations are observed in nephrosis, acromegaly, and after androgen or corticosteroid therapy. Familial hyper- or hypo-thyroxine-binding-globulinemias have been described. The incidence of TBG deficiency is approximately 1 in 9000. Certain drugs such as salicylates inhibit the protein-binding of T_4. In such cases, the unbound (free) hormone should be measured. Alternatively, an indirect measure of free thyroxine, such as the FT_4I may be used.

2. Medicinal or dietary iodine interferes with *in vivo* tests of radioiodine uptake, producing low uptakes which may not indicate a true decrease in hormone synthesis.

3. Persistent clinical and laboratory evidence of hypothyroidism despite an adequate replacement dose suggests either poor patient compliance, impaired absorption, drug interactions, or decreased potency of the preparation due to improper storage.

Carcinogenesis, Mutagenesis, and Impairment of Fertility Although animal studies to determine the mutagenic or carcinogenic potential of thyroid hormones have not been performed, synthetic T_4 is identical to that produced by the human thyroid gland.

A reported association between prolonged thyroid hormone therapy and breast cancer has not been confirmed and patients receiving levothyroxine sodium for established indications should not discontinue therapy.

Pregnancy: Pregnancy Category A. Studies in pregnant women have not shown that levothyroxine sodium increases the risk of fetal abnormalities if administered during pregnancy. If levothyroxine sodium is used during pregnancy, the possibility of fetal harm appears remote. Because studies cannot rule out the possibility of harm, levothyroxine sodium should be used during pregnancy only if clearly needed.

Thyroid hormones cross the placental barrier to some extent. T_4 levels in the cord blood of athyroid fetuses have been shown to be about one-third of maternal levels. Nevertheless, maternal-fetal transfer of T_4 may not prevent *in utero* hypothyroidism.

Hypothyroidism during pregnancy is associated with a higher rate of complications, including spontaneous abortion and preeclampsia, and has been reported to have an adverse effect on fetal and childhood development. On the basis of current knowledge, SYNTHROID® (levothyroxine sodium, USP) should therefore not be discontinued during pregnancy, and hypothyroidism diagnosed during pregnancy should be treated. Studies have shown that during pregnancy T_4 concentrations may decrease and TSH concentrations may increase to values outside normal ranges. Postpartum values are similar to preconception values. Elevations in TSH may occur as early as 4 weeks gestation.

Pregnant women who are maintained on SYNTHROID should have their TSH measured periodically. An elevated TSH should be corrected by an increase in SYNTHROID dose. After pregnancy, the dose can be decreased to the optimal preconception dose.

Nursing Mothers Minimal amounts of thyroid hormones are excreted in human milk. Thyroid hormones are not associated with serious adverse reactions and do not have known tumorigenic potential. While caution should be exercised when SYNTHROID is administered to a nursing woman, adequate replacement doses of levothyroxine sodium are generally needed to maintain normal lactation.

Pediatric Use: Congenital hypothyroidism Rapid restoration of normal serum T_4 concentrations is essential for preventing the deleterious effects of neonatal thyroid hormone deficiency on intelligence, as well as on overall growth and development. SYNTHROID should be initiated immediately upon diagnosis, and is generally continued for life. The goal of therapy is to maintain the serum total T_4 or FT_4 in the upper half of the normal range and serum TSH in the normal range.

An initial starting dose of 10 to 15 mcg/kg/day (ages 0-3 months) will generally increase serum T_4 concentrations to the upper half of the normal range in less than 3 weeks. Clinical assessment of growth and development and thyroid status should be monitored frequently. In most cases, the dose of SYNTHROID per body weight will decrease gradually as the patient grows through infancy and childhood (see Table). Prolonged use of large doses in infants may be associated with later behavior problems.

Thyroid function tests (serum total T_4 or FT_4, and TSH) should be monitored closely and used to determine the adequacy of SYNTHROID therapy. Normalization of serum T_4 levels is usually followed by a rapid decline of TSH levels. Nevertheless, normalization of TSH may lag behind normalization of T_4 levels by 2 to 3 months or longer. The relative elevation of serum TSH is more marked during the early months of therapy, but can persist to some degree throughout life. In rare patients TSH remains relatively elevated despite clinical euthyroidism and age-specific normal levels of total T_4 or FT_4. Increasing the SYNTHROID dosage to suppress TSH into the normal range may result in overtreatment, with an elevated serum T_4 level and clinical features of hyperthyroidism, including irritability, increased appetite with diarrhea, and sleeplessness. Another risk of prolonged overtreatment in infants is premature cranial synostosis.

Assessment of permanence of hypothyroidism may be done when transient hypothyroidism is suspected. Levothyroxine therapy may be interrupted for 30 days after 3 years of age and serum measurement of T4 and TSH levels obtained. If T_4 is low and the TSH level is elevated, permanent hypothyroidism is confirmed and therapy should be re-instituted. If T_4 and TSH remain in the normal range, a presumptive diagnosis of transient hypothyroidism can be made. In this instance, continued clinical monitoring and periodic reevaluation of thyroid function may be warranted.

Acquired hypothyroidism. The initial dose of SYNTHROID varies with age and body weight, and should be adjusted to maintain serum total T_4 or free T_4 levels in the upper half of the normal range. In general, in the absence of overriding clinical concerns, children should be started on a full replacement dose. Children with underlying heart disease should be started at lower doses, with careful upward titration. Children with severe, long-standing hypothyroidism may also be started on a lower initial dose with upward titration in an attempt to avoid premature closure of epiphyses. The recommended dose per body weight decreases with age (see Table).

Treated children may resume growth at a rate greater than normal (period of transient catch-up growth). In some cases catch-up growth may be adequate to normalize growth; however, in children with severe and prolonged hypothyroidism, adult height may be reduced. Excessive thyroxine replacement may initiate accelerated bone maturation resulting in disproportionate advancement in skeletal age and shortened adult stature.

Assessment of permanence of hypothyroidism may be done when transient hypothyroidism is suspected. Levothyroxine therapy may be interrupted for 30 days and serum measurement of T_4 and TSH levels obtained. If T_4 is low and the TSH level is elevated, permanent hypothyroidism is confirmed and therapy should be re-instituted. If T_4 and TSH remain in the normal range, a presumptive diagnosis of transient hypothyroidism can be made. In this instance, continued clinical monitoring and periodic reevaluation of thyroid function may be warranted.

ADVERSE REACTIONS Adverse reactions other than those indicative of thyrotoxicosis as a result of therapeutic overdosage, either initially or during the maintenance periods, are rare (see **OVERDOSAGE**). Craniosynostosis has been associated with iatrogenic hyperthyroidism in infants receiving thyroid hormone replacement therapy. Inadequate doses of SYNTHROID may produce or fail to resolve symptoms of hypothyroidism. Hypersensitivity reactions to the product excipients, such as rash and urticaria, may occur. Partial hair loss may occur during the initial months of therapy, but is generally transient. The incidence of continued hair loss is unknown. Pseudotumor cerebri has been reported in pediatric patients receiving thyroid hormone replacement therapy.

OVERDOSAGE: Signs and Symptoms: Excessive doses of SYNTHROID result in a hypermetabolic state indistinguishable from thyrotoxicosis of endogenous origin. Signs and symptoms of thyrotoxicosis include weight loss, increased appetite, palpitations, nervousness, diarrhea, abdominal cramps, sweating, tachycardia, increased pulse and blood pressure, cardiac arrhythmias, tremors, insomnia, heat intolerance, fever, and menstrual irregularities. Symptoms are not always evident or may not appear until several days after ingestion.

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CORRECTION

Elsie Booker appreciated being recognized as North Carolina's first female pharmacist. According to Alice Noble's book "The School of Pharmacy of the University of North Carolina, A History", the first women students were admitted to UNC School of Pharmacy in 1916 (pg. 61). This was even before Elsie Booker started pharmacy school. When Elsie notified us that women pharmacists were practicing before her, she also invited our members to visit her at Patterson Mills Country Store where she has her personal pharmacy museum on display.

CREDIT

A special thanks goes to Blake Madden, photographer, who provided all of the photographs used in the Asheville Project article in the July/August. His credit line was inadvertently left off.

Closing dates for classified advertising is the first day of the month preceding the month of issue. Ads are free for current NCPhA members if indicated when placing the ad. The non-member rate is .50¢ a word with a $10 minimum. Send ads to Carolina Journal of Pharmacy, c/o NCPhA, P.O. Box 229, Chapel Hill, NC 27514-0229 or fax to 919-968-9430.

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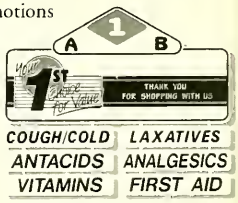

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A student at the University of North Carolina at Chapel Hill, for being selected to participate in the 1998 SmithKline Beecham Summer Internship program.

Jessica C. Pitt was one of four pharmacy students chosen to participate in this 12-week industry summer internship program. This is the 25th year that SmithKline Beecham has offered an annual summer internship program for pharmacy students. During that time, over 70 students have spent their summers working and learning in Philadelphia. Pharmacy students are selected for the program based on their applications, achievements, and faculty recommendations.

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Voice and Vision

"This is a difficult assignment, and I know you will procrastinate, so you need to start today." — Dr. Arnold House

by Dan Garrett

The day before my ninth grade Christmas vacation the biology teacher gave each person in the class a preserved frog. Our assignment was to dissect the frog and return to class the first day after the break with the skeleton of the frog mounted and all of the bones labeled. There was much whining to the teacher that this was a complicated and time consuming task that would take weeks to complete. The teacher responded by stating, "I realize this is a difficult assignment, and I know you will procrastinate, so you need to start today." Everyone in the class returned with their frog's bones two weeks later.

We have been talking about the unification of pharmacy in North Carolina for years. We are past the point of procrastination and have now begun. Every pharmacist in our state needs to be aware of and involved in the most significant event in North Carolina pharmacy history since the legislature enacted the Pharmacy Practice Act in 1880. Pharmacy leaders from across the state have begun dissecting their special interest organizations and are working to build a new skeleton to support ***One Voice-One Vision 2000*** for our profession. We need the input and commitment of pharmacists from Murphy to Manteo to help create our new structure and more importantly to create an organization that will meet our new mission...*To unite, serve and advance the profession of pharmacy for the benefit of society.* Over 120 pharmacists met on Oct. 15-16 to establish the task forces to build our new organization. Their job is daunting and we need your contribution. Please read the article on the unification process, and let us know on which task force you would like participate.

Our next state pharmacy meeting will be on Feb. 11-12, 1999, in Greensboro. This will be our first major joint meeting, and the theme will be **unification**. The program for the meeting has been planned as a collaborative effort of the NCPhA, NCSHP and NCASCP program committees. We will have presentations by Chris Decker, executive director of the Pharmacists' Society of Wisconsin; Bruce Canaday, president of ASHP, and Witt Moose, president-elect of NCPA, on the national perspective and impact of our proposed new organization. There will be a town hall meeting to get your views. Different educational tracks will focus on community, health system and consultant topics. Please mark your calendars to attend this important meeting.

UNITY: The Presidents of each pharmacy group stand together at the Unification Meeting. (Left to right - Tim White, NCPhRA; Steve Novak, NCSHP, Jane Thompson, NCASCP; Keith Elmore, NCPhA.)

We have continued to have representatives of the NCSHP Board and the NCPhA Executive Committee attend local pharmacy association meetings around the state. NCCPC has facilitated six regional programs on innovation. These meetings have provided us with valuable feedback on the unification process. We are developing our new organizational model on the premise of formal relationships with local associations and the formation of a House of Delegates with statewide representation. Committee meetings on Legislation and Regulations, Finance, Communications and Membership have been held jointly between NCSHP and NCPhA, and members are proving that by coming together we can work toward common goals.

An exciting development in our state is the formation of a local pharmacist independent practice association (IPA) in Greensboro and a statewide preferred provider organization (PPO) to contract for cognitive pharmacy services by networks of credentialed pharmacists. The model that is emerging is mutually supportive business entities of local IPA's coordinated with a state PPO to provide the strength needed to market and deliver reimbursable pharmacist clinical services. This is your opportunity to change pharmacy from a strictly commodities business to a knowledge provider that is paid for professional consultative services.

Unification, conducting joint meetings and establishing pharmacist provider networks are difficult and complex tasks. We have begun to make our dreams a reality. How can you help? Join us in this transformation by starting today!

A Lifetime of Achievment, A Night to Celebrate

by Peter Kanipe

The pharmaceutical industry has had a big year in 1998 with the introductions of Viagra, Tamoxifen and other significant drug breakthroughs. Pharmacist Jimmy S. Jackson of Garner has also had a big year, and he was honored as the "1998 Pharmacist of the Year" at the North Carolina Pharmaceutical Association's Mortar and Pestle Award Dinner on Sept. 18.

Jackson's award was announced at NCPhA's 118th Annual Convention in May for his distinguished service in pharmacy, public health and community involvement.

"I know I won an award for my service, but to me, it's a duty," Jackson said. "The award means a lot because it came from my peers."

The celebration was kicked off with a round of golf and ended with a special breakfast at the Jacksons' home the next morning. The actual ceremony was held at the Capital City Club in Raleigh with Master of Ceremony Robert Henry presiding. Many special guests were on hand to see NCPhA President Keith Elmore recognize Jackson as Pharmacist of the Year, including the mayor of Garner, Don Rohrbaugh, and U.S. Sen. Lauch Faircloth.

Jackson, a native of Philadelphia, Miss., graduated from the University of Mississippi with a degree in pharmacy in 1967. He then moved to Garner to work as an intern with Kerr Drug Inc., beginning a relationship that would last for nearly 30 years. Jackson became a store manager when Kerr opened a new pharmacy in Garner in 1969. From there, he moved up to district manger and director of pharmacy until he became vice president of pharmacy and government affairs in 1990.

(left) Friends and colleagues of Jimmy Jackson enjoy a day on the greens. (lower right) NCPhA director Dan Garrett (seated) and Jimmy mix and mingle at the Capital City Club. (lower left) Jimmy draws his weapon.

After the acquisition of Kerr by Thrift Drug Co. in 1995, Jackson became regional sales manager of TDI Managed Care Services Inc., a division of Kerr & Thrift Drugs. He has served as vice president of pharmacy relations at Eckerd Corp. since 1997 when the company was acquired by Thrift Drug.

Jackson is a strong advocate for community service because he said pharmacists play a key role in deciding how some issues should be handled. "We need to be encouraging people to get involved in the legislature. Pharmacists are important people in the community," Jackson said. "Pharmacists have a responsibility to give something back. The community gives so much to you."

He has remained active in numerous professional associations for many years. Jackson is the immediate past president and former Don Blanton Award winner for NCPhA, an association in which he has been a member since 1975.

Jackson is also a member of the National Association of Chain Drug Stores, a group that has 66,000 members and represents grocery and drug stores across the nation. He has served on the Pharmacy Affairs Committee and serves on the Government Affairs Committee.

Jackson won the NACDS 1997 Harold W. Pratt Award, chain pharmacy's highest honor for pharmacists, for distinguishing himself in the field of pharmacy and making a lasting contribution to the industry. He was cited for "always finding the time to help others in the industry and making the industry better for all of us" in being chosen for the award.

That citation Jackson received in 1997 seems to summarize his devotion to his community as well. While he has worked hard on improving the field of pharmacy, he also strives to improve the standing of his community. Jackson serves on the Rotary Club, the Garner Chamber of Commerce and several other city committees at the re-

quest of the Garner mayor.

But his service to help people and his profession does not stop there. Jackson plays a major part in promoting the education of future pharmacists.

"There is another side of Jimmy, one that too few people see, and that is his commitment to today's pharmacy students," said Bill Campbell, dean of the University of North Carolina School of Pharmacy. "I have been privileged to see Jimmy as a tireless advocate of pharmacy students, both in expanding their career opportunities and in helping meet their current needs through scholarship and other financial support."

Jackson continues to live in Garner with the former Peggy Williamson, his wife of 29 years. The couple has two daughters.

"Jimmy has always kept the profession of pharmacy first and foremost in his career," his wife said. "He's very honored and humbled by this. He did what he wanted to do. He didn't do it to receive this honor."

The Mortar and Pestle Award is sponsored by the North Carolina Pharmaceutical Association. NCPhA's mission is "to unite, serve and advance the profession of pharmacy."

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Progress Report: Top Priorities for Unification

"Focus on the process and the outcome will take care of itself."
Bennett Simms

The presidents and presidents-elect of NCSHP, NCPhA, NCASCP and NCRPhA have joined together to form a driving committee for the unification process (see page 19). Each of these organizations have contributed financially to hire a facilitator to help us achieve our common goals. Executive Director Dan Garrett serves as an ex-officio member of the driving committee and has been charged by these leaders "to make the unification happen." Note that this is a *driving* committee and not a *steering* committee. A target date for creation of the new North Carolina pharmacy organization has been set for Jan. 1, 2000, in order to achieve *One Voice-One Vision 2000.* The idea for having a driving committee was *stolen* from UNC pharmacy students who came together to establish one pharmacy student organization for the UNC School of Pharmacy in 1998. The driving committee is responsible for the unification process, and they have established a mission and vision for the new organization, formed task forces to develop detailed plans and are working on the new organizational structure. The driving committee will meet periodically to make sure things are on track and to resolve any issues in a collaborative manner.

Mission of the New NC Pharmacy Organization

This organization exists to unite, serve and advance the profession of pharmacy for the benefit of society.

Vision of the the New NC Pharmacy Organization

This organization will be recognized as a leader in providing services for our members which foster the development of advanced pharmacy practice to improve the health of the people we serve.

More than 120 members representing all pharmacy groups met in Chapel Hill on Oct. 15 -16, 1998. Joint and individual committee meetings were held on the 15th. Each committee worked on their activities for 1998, discussed their perspectives and suggestions for the unification process and reported these to the entire group. A barbecue dinner was held at Storybrook Farm that evening to provide an opportunity to expand our professional network.

Eight task forces were convened on the 16th (see attached chart of task forces and leaders). The presidents of each of the organizations gave a history of their groups and shared their commitment to the unification process. The new mission and vision, along with a draft of the proposed organizational structure was presented. The task forces were then given specific assignments for discussion and were asked to add any other topics and return with a report on their top three priorities. The driving committee has established a March 1, 1999, target for completion of the task force work, and most groups thought this was achievable. It is essential for the task forces to complete their work by early spring of 1999 to allow membership of all organizations to review and approve the new organization.

Involvement, contribution and support from members in all current organizations are the keys to success of the unification. The driving committee appointed the task force chairs for each task force based on their interest and expertise. Each driving committee member is a liaison to one of the task forces. We **need more members on each task force and you can join by contacting the task force chair or Dan Garrett.** This is a once in a lifetime opportunity to help shape your profession's future.

Committee	*Task Force Chair/Driving Committee Liaison*	*Priority*
Constitution/Bylaws	Virginia Lockamy (NCPhA)/Steve Novak (NCSHP)	Leadership from all organizations
Education	Anna Garrett (NCSHP)/Margaret Sgritta (NCASCP)	Meet needs of all practitioners
Finance	Randy Ball (NCPhA)/Keith Elmore(NCPhA)	Conduct audit of each org.
Legal/Regulatory	Ken Burleson (NCSHP)/Mike James (NCRPhA)	Infrastructure for unified voice
Marketing/Comm. Vote Yes!	Jennifer Burch (NCPhA)/Kevin Almond (NCPhA) Tim White (NCRPhA)	Vote Yes! survey to focus mktg. Web site/communications
Membership	Beth Williams (NCSHP)/Jane Thompson (NCASCP)	+ 25%/year with 100% pharmacists
Professional Relations	Mike List (NCASCP)/Bill Harris (NCSHP)	Plan to build up relationships
Transition. Dissolution, Operations	Joe Moose (NCPhA)/ Dan Garrett (NCPhA/NCSHP)	Retain lawyer to create new entity and dissolve old

* Only one priority per committee was listed due to space

1999 Pharmaceutical Directory

Local Pharmaceutical Associations

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Contact, Jack G. Watts, P.O. Box 458, Burlington, NC 27216-0458, (336) 227-8662
Meets every 4th Wednesday night at the Cutting Board.

BLUE RIDGE PHARMACEUTICAL ASSOCIATION
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e-mail: critzsteve@aol.com
Vice Pres., Larry Irwin, 411 Hawthorne Road, Elkin, NC 28261, (336) 835-6627
Sec., Lois Koontz, P.O. Box 1205, Jefferson, NC 28640, (336) 982-3401

CAPE FEAR PHARMACEUTICAL SOCIETY
INFORMATION NOT AVAILABLE

CATAWBA VALLEY SOCIETY OF PHARMACISTS
INFORMATION NOT AVAILABLE

CLEVELAND COUNTY PHARMACEUTICAL ASSOCIATION
Contact Person/Leader, Fern Douglas Potts, 330 Tremont Place, Shelby, NC 28150, (704) 487-0235
Co-leader, Lori Wilson, 1704 Country Garden Drive, Shelby, NC 28150, (704) 484-8808
Meets monthly at the Cleveland Country Club Sundays at 7 p.m. from September to November and from January to May.

COLUMBUS-BLADEN-HORRY PHARMACEUTICAL ASSOCIATION
Pres., John Watson, 204 Anderson St., Tabor City, NC 28463, (910) 642-4250
e-mail: jwatsonrph@interstar.net
Vice Pres., Sterling Koonce, 7 Pireway Road, Tabor City, NC 28463, (910) 653-4800
Sec.-Treas., Mary Hooks, 1301 Miller Circle, Whiteville, NC 28472, (910) 642-2250

DAVIDSON COUNTY PHARMACEUTICAL ASSOCIATION
INACTIVE

DOWN EAST PHARMACY SOCIETY
INACTIVE

DURHAM-ORANGE PHARMACEUTICAL ASSOCIATION
Pres., Jennifer Burch, 2 Drysdale Court, Durham, NC 27713, e-mail: jeburch@aol.com
Sec.-Treas., Vince Stevens, 8408 Inverness Way, Chapel Hill, NC 27516, (919) 933-0583
Meets at the Willowhaven Country Club.

GUILFORD COUNTY SOCIETY OF PHARMACISTS
Contact, Frank Burton, 120 E. Lindsay St., Greensboro, NC 27401, (336) 272-7139
e-mail: burtonrx@juno.com
Meets at Cone Hospital, AHEC Room 1040 at 7:30 p.m. on the second Sunday night of each month.

HIGH COUNTRY PHARMACY SOCIETY
INACTIVE

LINCOLN COUNTY PHARMACEUTICAL ASSOCIATION
Pres., Harry L. Brogden, 105 Labans Lane, Lincolnton, NC 28092, (704) 735-9867
Sec., David Keever, 696 Springside Drive, Lincolnton, NC 28092, (704) 735-0535
Meets every third Sunday night at 7:30 at the Lincoln Medical Center except June, July, August and December.

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1st Vice Pres., Carla Ferrara, 6407 Mock Orange Drive, Charlotte, NC 28277, (704) 342-8181
2nd Vice Pres., Debbie Smith, 3200 E. Ford Road, Charlotte, NC 28205, (704) 535-3908
Sec., Anjali Jackson, 4400 Winedale Lane,

Local

Charlotte, NC 28205, (704) 844-8875
Meets second Thursday of each month from January to May and from September to November.

MOORE COUNTY PHARMACEUTICAL ASSOCIATION
Pres., Wanda Crenshaw, 182 Bridgewater Drive, Southern Pines, NC 28387, (910) 944-5773
Sec.-Treas., Ralph Cole, 15 Baltusrol Lane, Pinehurst, NC 28374, (910) 295-6961
Meets on the third Thursday of each month from September to May at 7 p.m. at Dunes Table.

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Pres., Marty Beasley, 1206 North 23rd St., Wilmington, NC 28405, (910) 251-6701
email: marty.beasley@aaiintl.com
Sec.-Treas., Tonia LeCroy, 5454 Eastwind Road, Wilmington, NC 28403, (910) 395-6089
Meets the second Tuesday of each month at 7 p.m.

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Vice Pres., Noel Pope, 302 Fairlane Drive, Grifton, NC 28530, (252) 524-5323
Meets at the Holiday Inn in Williamston on the second Wednesday of every other month (except December) at 7:30 p.m.

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Pres., Mike Brewer, 2106 Polo Road, Winston-Salem, NC 27106, (336) 718-1040
Vice Pres., Julie Kirk, (336) 716-9406
Vice Pres., Jeff Lippow, (336) 718-5666

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e-mail: moosedrug1@ctc.net
Sec.-Treas., Laura Dillard, P.O. Box 4113, Concord, NC 28025, (704)782-2425

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INACTIVE

RICHMOND PHARMACEUTICAL ASSOCIATION
INACTIVE

ROCKINGHAM COUNTY SOCIETY OF PHARMACISTS
Pres., Keith Layne, 1300 Towncreek Road, Eden, NC 27288, (336) 623-8200
Vice Pres., Andy Gaster
Meets at Morehead Hospital on the third Sunday of each month at 7 p.m.

RUTHERFORD COUNTY PHARMACEUTICAL ASSOCIATION
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Meets Tuesday nights at Rolling Hills Country Club.

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WAYNE COUNTY PHARMACEUTICAL SOCIETY
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WILSON COUNTY PHARMACEUTICAL ASSOCIATION
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AHECs

The Neurobiology of Addiction

by Dave Marley

A person's initial decision to use alcohol or other drugs (AODs) is influenced by genetic, psycho-social and environmental factors. Once ingested, however, the drug itself can encourage its continued use through direct action on the nerve cells of the brain.

According to Drs. Amanda J. Roberts and George F. Koob, the processes that lead to drug-seeking behavior and addiction result partly from altered communication among nerve cells and partly from activation of the brain's regions involved in the body's response to pleasurable stimuli. These researchers postulate that a residual state of craving persists after stopping AOD use, which may prompt release, even in long-term abstainers. Research is beginning to reveal how specific brain regions may be integrated to form neural circuits that modulate aspects of addiction. This knowledge will aid in the development of improved treatment therapies.

Communication among brain cells plays a pivotal role in controlling the body's functions, including movement, learning, memory and thought. Accordingly, AOD-induced disruption of this communication is the basis for many of AOD's effects on the body, particularly the brain. Nerve-cell communication is mediated by chemicals that excite or inhibit the impulse-receiving nerve cells (i.e., neurotransmitters) or modify the effects that neurotransmitters have on the impulse-receiving cells (i.e., neuromodulators).

In a recent paper, Dr. Gaetano Di Chiara describes the distribution and function of the neurotransmitter dopamine in the brain. Through its actions on the brain's "reward center," dopamine may contribute to motivation and reinforcement of alcohol consumption.

Another neurotransmitter affected by alcohol is serotonin. According to Dr. David Lovinger, serotonin levels appear to be lower in the brains of alcoholics than in the brains of nonalcoholics. Serotonin also may promote alcohol's intoxicating and rewarding effects by interacting with other neurotransmitter systems (e.g., dopamine).

The brain's major excitatory neurotransmitter is glutamate. Alcohol inhibits some of the receptors that mediate glutamates actions. These effects may account in part, for the cognitive dysfunction associated with alcoholism.

Another area being researched is alcohol's effects on gamma-aminobutyric acid (GABA), the primary inhibitory neurotransmitter, and its main receptor: the $GABA_A$-receptor. Enhanced $GABA_A$-receptor function may be responsible for alcohol's sedative effects. Moreover, alcohol induced changes in the $GABA_A$-receptor function may contribute to alcohol dependence and tolerance, and abnormalities in the GABA system may contribute to the predisposition to alcoholism.

Among the neuromodulators affected by alcohol are endogenous opioid peptides. These chemicals may play a significant role in mediating alcohol reinforcement and excessive alcohol consumption. Consequently, medications that interfere with opioid-peptide functioning, such as naltrexone, can be important components of alcoholism treatment.

As pharmacists, we have a responsibility to constantly update our knowledge-base on disease states and therapeutics. Today, more than ever, the analogy applies that an alcoholic unable to correctly process alcohol, resembles the diabetic unable to correctly process sugar. We are at a point now, with the research being done in the field of addiction, that it is professionally irresponsible to recognize alcoholism and drug addiction as anything other than a chronic, progressive and treatable disease.

Dave Marley is the executive director of NCPRN, the North Carolina Pharmacist Recovery Network. NCPRN is a non-profit organization dedicated to the early identification, intervention and treatment of impaired pharmacists and pharmacy students in the state.

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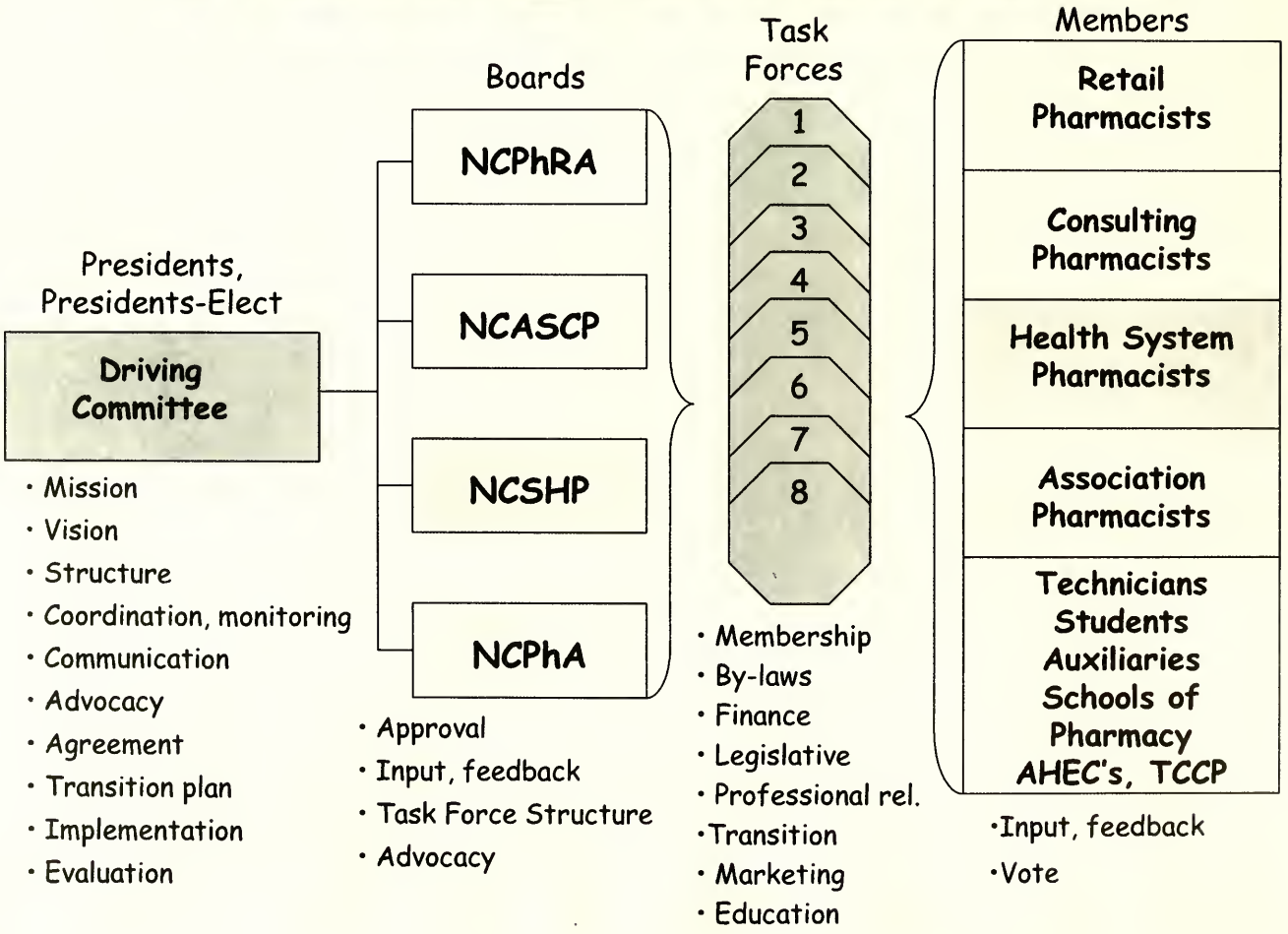

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NORTH CAROLINA SOCIETY OF HEALTH-SYSTEM PHARMACISTS
NCSHP
Newsletter

Volume 21, Number 6 The bimonthly publication of the North Carolina Society of Health-System Pharmacists November/December 1998

Annual Carolina Seminar 1998

by Frances Gualtieri

More than 700 pharmacists, pharmacy technicians, pharmaceutical exhibitors, residency showcase exhibitors and pharmacy students interested in residencies participated in the NCSHP/UNC Annual Carolina Seminar on Oct. 8-9 in Greensboro. A bonus for non-NCSHP member participants was the complimentary NCSHP membership available with registration for the complete CE program offered.

Almost 600 pharmacists and pharmacy technicians attended the first morning's sessions which focused on managing patients with diabetes. The pharmacists spent the afternoon session in a managed care versus managed cost educational session. A NCSHP business meeting followed the morning's program and included a financial update on this year's activities as well as the presentation of the 1999-2000 officer and board of directors candidate slate.

Following the educational session four pharmacists from different geographical locations and types of hospitals in North Carolina conducted a panel discussion of their individual practice situations and their applications of today's economics with respect to patient care. A rousing "Pearls Session" rounded up the day's CE activities with nine NCSHP pharmacists presenting a variety of clinical and administrative issues in a quick-to-the point and often humorous manner.

"A rousing Pearls Session rounded up the day's CE activities with nine NCSHP pharmacists presenting a variety of clinical and administrative issues in a quick-to-the point and often humorous manner."

Presentations at the pharmacy technicians' afternoon CE program included an update on NC pharmacy rules and regulations and proposed changes to these rules. The technicians also enjoyed an update on total parenteral nutrition and a general information session on the use of botanicals in healthcare. Pharmacy technicians continue to be one of the most enthusiastic of the NCSHP CE program participants and are especially vocal at evaluating the programs and recommending new CE topics.

The evening exhibits and residency showcase session was enthusiastically attended by meeting participants. Forty registered exhibits were staffed with more than 100 exhibitors including pharmaceutical product manufacturers, pharmaceutical equipment distributors and pharmaceuticals distributors.

There continues to be a growing interest in the residency showcases with close to 100 participants involved in this year's program. Residents in current programs, along with their directors, engaged prospective residents in discussions of their program's high-

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NC Pharmacacy Winter Meeting

One Profession. Many Practitioners. Many Competencies.

The North Carolina Pharmacy Winter Meeting, a combination of NCSHP's Winter Meeting and NCPhA's Socio-Economic Meeting, will mark the first joint pharmacy meeting in the state's history. Hundreds will gather on Feb. 11-12, 1999, at the Four Seasons Holiday Inn and Convention Center in Greensboro to learn more about other states' path to unifying pharmacy organizations and to study specific practice skills in specialized small groups to help better serve patients in each applicable setting.

In the morning sessions, leaders of the Pharmacists' Society of Wisconsin will present firsthand their successful story of unification. Leaders of each pharmacy group in North Carolina then will address the participants on their own excitements and trepidations about proceeding with unification. Immediately following will be a "town meeting" where participants can address presidential officers of each group with questions and concerns.

Four quality continuing education workshops will be held in the first afternoon focusing on specific pharmaceutical care skills to monitor patients, specifically to serve diabetics, meet women's health needs and assist patients receiving newer agents to treat CNS disorders. The second day will feature ten 1 1/2-hour workshops where, in small groups, pharmacists can learn specific pharmaceutical care skills to directly assist patients with immunizations, obesity, asthma/COPD, smoking cessation, dyslipidemias, anticoagulant therapy, diabetes, alternative medicines and more.

Mark Feb. 11-12 on your calendar and plan to be in Greensboro for one of the most exciting statewide pharmacy meetings ever.

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Dilemmas

An Environment of Change

by Ernie Keich, MHS, RPh
Rowan Regional Medical Center

Several events occurred recently which caused me to reflect on the future of pharmacy. The first was the disregard shown for the profession by HCFA by practically eliminating any reference to pharmacists in the proposed revisions for hospital participation. The last minute appeal by pharmacy organizations to members for letters of protest was indicative that we as a profession were caught off guard by the HCFA action. The HCFA session at the ASHP annual meeting also made clear the fact that pharmacy representation at HCFA borders on nonexistent.

The second concern was a commentary that appeared in the June 15, 1998, publication of the AJHP journal. The article "Institutional and Contingency Approaches to the Reprofessionalization of Pharmacy" presents arguments as to whether pharmacy should be regarded as a "profession" or if it is actually an "occupation."

Also questioned was the concept of pharmacists fostering the "rational myth" of themselves as drug experts. The authors pointed out that pharmacy no longer was a monolithic profession and that there was diversity in educational needs mandated by the difference in practice environments. They questioned the decision that the profession has made by restricting itself to one educational tract; the lack of flexibility might actually hinder pharmacy's chance of survival. The article was excellent in that by questioning the fundamentals on which the profession is based it makes us re-examine the paths on which pharmacy has chosen to embark.

Finally, here's an observation of the ASHP annual meeting. If you had any doubt of how the focus of pharmacy has changed, all you had to do was visit the Exhibit Hall. Ten years ago the floor space was dominated by pharmaceutical companies. At the June 1998 meeting, displays of automation and information management were more numerous and prominent than those of drug companies. The "unspoken" message was clear: if your practice is centered around the handling of medications, your services will soon be of limited demand. As a profession we must continue to redirect ourselves before we are a casualty in the "Land of Robots."

Continued from page 21

lights and options for residency candidates. Comments from prospective residents included how informative the showcases were and how participants came into the showcase exhibits with preconceived ideas which were very realistically updated and corrected for today's practice environment.

Leading off the second day's pharmacists' programming was a morning session devoted to updates on low molecular weight heparin use in inpatients and outpatients. Following this introductory talk was the cardiology implications and risk stratification and prophylaxis with low molecular weight heparin therapy. Pharmacotherapy updates closed the day's CE programming. Included in the afternoon session was an update on quinolones and on HIV.

The NCSHP/UNC Annual Carolina Seminar continues to offer a significant amount of CE programming for North Carolina (and surrounding states) pharmacists and pharmacy technicians. The NCSHP Program Committee is committed to offering quality CE requested by its members either on program evaluations or by written comments directly to the NCSHP Program Committee in care of the NCSHP office. If you wish to learn more on a particular topic or want a new topic to be covered at CE programming make sure and let us know. And, it's always a bonus if you can also recommend an expert who may be willing to share this information in a CE program format.

From the President

The Patient is Waiting

Initial results are in from the member survey on "Unification of Pharmacy Organizations in North Carolina," distributed at the NCSHP Carolina Seminar in Greensboro this October. Of the 172 surveys returned, 147 respondents (85.5%) supported the concept of unification, 21 (12.2%) were opposed, and 4 (2.3%) were unsure. This response is significant in that it represents about 30% of our membership. It validates our decision to move forward.

Before, during and after the Greensboro meeting, there was a lot of conjecture on how NCSHP should approach unification discussions. What's best for NCSHP? How do we retain ASHP affiliation? How do we maintain effective representation in the new organization? How do we provide more diverse pharmacy continuing education? How will unification affect membership dues? Which mindset do we need to adopt as we move forward towards a unified organization? We will evaluate the survey further to provide additional direction to the Board and officers as we begin discussions with the other pharmacy organizations toward unification. I talked to a lot of people in Greensboro, and I received a lot of opinions on what type of organization the unified organization should be - an academy model like Indiana , a new entity like Wisconsin, or some other organizational form. But the best answer came from one of my pharmacists. When asked on what type of organization we should form, he simply responded, "whichever one is best for the patient." At first I thought his answer naive, but the more I thought about, I realized it was the most significant answer. The primary framework we need to use in evaluating organizational structures is the one which allows us to move forward to best serve the patient. Improving patient care needs to be the superordinate interest that transcends the individual interests of all the organizations involved.

NCSHP President Steve Novak, MPA

In his 1998 Harvey A.K. Whitney Lecture, "The Patient is Waiting," John Gans comments, "Are we as willing to accept responsibility for society's drug therapy problems as our past leaders were willing to accept responsibility for the issues of their day? These problems are real. How many exposés in US News and World Report, Dateline and Prime Time Live will we endure before we realize that, if we do not accept responsibility for solving these problems, the public will find someone who will? We are the drug experts. We are the most trusted and accessible health care professionals. But the patient is still waiting for much more from pharmacists."

Given the changes in the healthcare delivery system - the movement to ambulatory care, managed care and continuity of care, one unified organization will consolidate resources and organizational energy to focus on the provision of pharmaceutical care to the patient. How much longer the patient has to wait depends on the type of organization we build. Although there are a lot of factors to consider, we must not linger too long on the building process, or the patient may not be there when we arrive.

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NCSHP members are encouraged to share their views, concerns and ideas with their colleagues by contributing articles to The NCSHP Newsletter. Opinions expressed are those of the author and may not represent the views of NCSHP, its officers, Board of Directors or its membership. Copy deadlines are the 10th of the month prior to the month of the next issue to be published. (i.e. April 10th for the May/June issue.)

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Clinical Consultant's Corner

John C. Rublein, PharmD
Infectious Diseases Fellow
Clinical Instructor, Division of Pharmacotherapy
University of North Carolina at Chapel Hill
School of Pharmacy

Since 1996, clinical pharmacists have been helping with patient care in the infectious diseases clinic at UNC Hospitals. The service began as a project for UNC Hospital's first infectious diseases pharmacotherapy fellow. The service has since been expanded to include a faculty member, three fellows, an infectious diseases resident, an ambulatory care resident and two pharmacy practice residents. Pharmacists are available during clinic hours five days a week.

Pharmacists in the clinic provide a variety of services, but the most important activity is intensive patient counseling. Current antiretroviral regimens are extremely complex and adherence is problematic. Additionally, adherence is one of the main determining factors for clinical outcome. Pharmacists in the ID clinic at UNC Hospitals are available when the primary care provider desires more intensive medication counseling for their patients. Pharmacists routinely utilize adherence aids such as medication calendars and pillboxes. Medication information is distributed via information sheets produced and developed by our pharmacists and directed toward our patients.

In addition to medication counseling, pharmacists are available to answer drug information questions. The development of protease inhibitor and non-nucleoside reverse transcriptase inhibitor classes of antiretrovirals has created many concerns about drug interactions. Both classes of antiretrovirals have varying effects on inhibition or induction of the cytochrome P450 enzyme system, leading to numerous clinically significant drug interactions. Pharmacists are often asked to assess the drug interaction potential for a medication being added to a patient's regimen.

Pharmacists have recently become involved with the coordination of the expanded access programs for new antiretrovirals. Through our efforts, more than 50 patients were given access to new medications when they had exhausted their options with approved medications. Pharmacists were available to explain these new medications, and help monitor patients for both clinical outcome as well as adverse events. Patients often utilize the pharmacist even after leaving the clinic when questions or potential adverse events arise at home.

The ID clinic has proven very useful as a site for student experiential rotations. As the HIV epidemic begins to move toward chronic disease management, experience with HIV infected patients and antiretroviral drug therapy will become increasingly valuable for pharmacists in all practice sites. Through our clinic involvement we have been able to expose students to this exciting area of pharmacy practice. The response has been overwhelmingly positive from the clinic staff as well as the students.

Finally, pharmacists have found numerous opportunities in the HIV clinic to expand knowledge in the area of HIV pharmacotherapy. Pharmacists have published results from a study of non-traditional therapy use and are currently working on studies regarding the reading ability of clinic patients, differences in medication tolerance, usefulness of a computer generated medication calendar and adherence improvement through self-management.

Clinics treating patients with HIV infection are ripe with opportunities for pharmaceutical care by pharmacists of all levels and experience. More and more HIV practitioners are realizing the value of medication counseling by a trained and experienced pharmacist. I encourage each of you to keep abreast of new antiretrovirals so that you will be available as a resource the next time you encounter a patient with HIV infection.

STAFF PHARMACISTS

Pitt County Memorial Hospital, part of University Health Systems of Eastern Carolina, is currently seeking Staff Pharmacists. Positions require a BS in Pharmacy or Pharm. D. with current NC Pharmacist license; residency or previous hospital pharmacy experience preferred. Current pharmacy services include I.V. admixture, decentralized unit dose distribution, drug information, nutrition support, chemotherapy and comprehensive pharmacy-based computer systems.

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NCSHP/NCPhA WEB SITE SURVEY

The North Carolina Society of Health-System Pharmacists (NCSHP) and the North Carolina Pharmaceutical Association (NCPhA) are currently considering the production of a joint Internet web site to serve as a source of communication and education for their members as well as for the general public. To this end, NCSHP and NCPhA are conducting a survey of pharmacists, pharmacy residents and pharmacy students to identify services and features to be included in the web site to make it most useful to all members. NCSHP and NCPhA would greatly appreciate you taking a few moments to fill out this brief survey and return it to NCSHP at the Institute of Pharmacy by fax at 919-968-9430.

Thank you for your input!

Please check the most applicable response:

1. Which best describes your current practice setting?

____ Chain Retail Store

____ Independent Retail Store

____ Hospital Pharmacy

____ Pharmaceutical Industry

____ Consultant Pharmacy

____ Long-term Care Facility

____ School of Pharmacy

____ Other (Please list):

_____

2. To which professional organizations do you currently belong? (Check all that apply)

____ NCSHP ____ NCPhA ____ ASHP

____ APhA ____ ACCP ____ AACP

____ NCPA ____ ASCP ____ Other (Please list):

_____

_____

3. Do you use the Internet for non-pharmacy related purposes (e-mail, shopping, news/information, etc.)?

____ yes ____ no

4. Do you use the Internet in your current pharmacy practice?
(If no, please skip to question #6)

____ yes ____ no

5. If yes, how frequently do you use the Internet for pharmacy-related purposes?

____ More than 4 times per day

____ 1-4 times per day

____ 1-4 times per week

____ less than once per week

____ Less than once per month

6. Have you ever visited the NCSHP web site (http://www.mindspring.com/~ncshp)?

____ yes ____ no

7. Do you ever visit the web site for other pharmacy organizations? (If yes, please select which ones.)

____ ASHP ____ APhA ____ ACCP

____ NCPA ____ ASCP ____ Other (Please list):

_____

_____

8. Please place a check next to any of the web site features you feel would be ***most*** useful in your practice? (Use the blank spaces for other suggestions)

Association/Society members info (Phone #s, e-mail address, etc.)	Residency opportunities	Information on investigational drugs/drugs coming to market
Historical background about the Society/Association	Chat rooms for practice areas (e.g., hospital, community, consultant, student, resident, JCAHO, management, etc.)	Updates on current issues in the lay news (e.g., recalls, new uses, etc.)
Mission statement	Links to other pharmacy-related websites (Board of Pharmacy, APhA, ASHP, UNC, Campbell, etc.)	Links to pharmaceutical companies
Meeting schedules (National, State and Local)	Links to other medical-related sites (FDA, CDC, AMA, etc.)	Online "lending library" (e.g., videos, educational materials, references)
On-line continuing education	Drug information resources (Medline, USPDI, Micromedex, etc.)	Legislative updates
Statewide schedules of future CE programs	Table of contents for *Carolina Journal of Pharmacy*	Online "voting" (e.g., Society and Association related issues and offices)
Interactive certification programs (e.g., asthma, diabetes, etc.)	Online *Carolina Journal of Pharmacy*	Evidence-based medicine, pharmacoeconomics and outcomes measurement tools
Committee information (members, charges, meetings, minutes, etc.)	Patient education materials	Online medication use evaluation criteria
Society/Association budget information	Disease state education modules	Online drug reviews (i.e., monographs)
Career opportunities within the state	Financial/business information (e.g., retirement planning, insurance, pharmaceutical industry forecasting)	JCAHO updates
Membership application	Listing of upcoming Society/ Association elections and candidates	Staff development programs

9. Would having access to a some or all of the services listed in #8 make you more likely to join a particular professional organization?

____ yes ____ no

THANK YOU FOR YOUR COOPERATON!

Tech Talk

David R. Work, the executive director of the North Carolina Board of Pharmacy, spoke to 130 pharmacy technicians at the 8th Annual Carolina Seminar during a one-hour session on "Contemporary Issues for the Pharmacy Technician" on Oct. 7 in Greensboro. Mr. Work reviewed the web site now in place for the Board (www.ncbop.org) which includes the following categories:

- Notice of Public Hearings
- Information about the Board of Pharmacy
- New Developments
- Proposed rule changes
- Four simple steps to reduce errors
- CE Credit for preceptors of students
- Revising fees
- Pharmacists workload
- Frequently asked questions
- Calendar of events
- Literature
- Search our site

Perhaps the most significant part of the web site is the feature on common questions and answers. This contains the more frequent inquiries of the Board from citizens and from pharmacy personnel and includes the following questions:

- How can a pharmacist know which companies are in compliance with the Board's rule on return of outdated drugs?
- What is the proper procedure for providing heparin, saline, sterile water for irrigation and hydration fluids to home health agencies?
- What is the proper procedure to follow when dispensing sample medications?
- When does the amendment to the Pharmacy Practice Act that pertains to narrow therapeutic index drugs go into effect?
- Is there a time limit between the date a prescription for a Schedule II drug is issued and the date when it may be filled?
- Is there a time limit on Schedule III and IV drugs?
- Is there a six month/five refill limit on Schedule V drugs?
- What grounds are listed in the Board rule on refusing to fill or refill a prescription?
- Does the phrase "Do you have any questions?" when directed at the patient satisfy the Board's requirement to counsel patients under the patient counseling rule?
- Are pharmacists required to "cancel" a prescription for a controlled substance by drawing a line from one corner to the other of the prescription document?
- What and where is PRN?
- How can I file a complaint?
- Can I get a generic version of my brand-name prescription?
- Can I get more information on my prescription from the pharmacist?
- Can a consumer get their prescription transferred from one pharmacy to another?

David Work
Executive Director, North Carolina Board of Pharmacy

Mr. Work also noted that the efforts to change the statute to provide for registration of pharmacy technicians was probably not going to pass in the General Assembly this year. Individuals who want to pursue that matter should work through the North Carolina Pharmaceutical Association to that end.

In a lively question and answer session following his presentation, he noted that pharmacy technicians are professional people and should not "take any crap." He noted that all people treating sick patients are entitled to their own respect and dignity and hospitals could not operate without pharmacy technicians.

Calendar of Events

December 6-10, 1998
ASHP Midyear Clinical Meeting
Las Vegas, NV

February 11-12, 1999
North Carolina Pharmacy Winter Meeting
Greensboro

May 20-23, 1999
NCPhA Convention
Atlantic Beach

June 6-10, 1999
ASHP Annual Meeting
Reno, NV

July 31-August 2, 1999
ASHP Home Care Meeting
Chicago, Ill

October 6-7, 1999
Annual Carolina Seminar
Greensboro

December 5-9, 1999
ASHP Midyear Clinical
Orlando, Fl.

Do you or someone you know deserve special recognition? Would you like to inform other pharmacists and technicians of an activity at your practice site?

If so, please send your information to the NCSHP office at: PO Box 968 Chapel Hill NC 27514 or NCSHP@mindspring.com.

We rely on our readers to keep us informed of our members' activities. Your help in locating future articles for the NCSHP Newsletter is greatly appreciated!

Ground-breaking for Kerr Hall at UNC-CH

Current students and alumni of the University of North Carolina at Chapel Hill School of Pharmacy participated in the school's ground-breaking ceremony on Oct. 12 for the new Banks D. Kerr Hall.

The ceremony heralded the start of an $18.2 million addition to Beard Hall, which houses the School of Pharmacy. The 65,000 square-foot, three-story building will feature technologically advanced classrooms and laboratories with interactive video and audio capability.

The event celebrated not only the construction of a new building but also the people who made that dream possible. More than 4,000 UNC School of Pharmacy alumni contributed to the fund raising campaign, including Banks D. Kerr, a 1943 honors graduate of the school and the founder and former chief executive officer of the Kerr Drug Store chain, who donated $2 million to the cause. Kerr and his wife, Dot, donated the largest individual gift ever made to the School. The NC General Assembly provided $11.2 million for the additional wing to the state's only public pharmacy school.

Despite the high-tech future of the pharmacy classrooms, the school's officials do not want the people to forget the historically customer-friendly, hands-on past that has earned pharmacists the title of most trusted professionals in the country for nine years running. As a reminder of the past, Sutton's Drug Store of Chapel Hill served homemade vanilla and cherry colas and lunch counter fare such as egg salad and grilled cheese sandwiches.

During the ceremony, UNC-CH School of Pharmacy alumni and students representing the state's 100 counties stood together in the shape of North Carolina to demonstrate the school's widespread influence. More than 7,000 pharmacists practice in 2,000 pharmacies all across the state.

The ground breaking took place on University Day at UNC-CH, which honors the laying of the cornerstone of Old East, the nation's first state university building, in 1793.

Fall 1999 Applications for UNC-CH External Doctor of Pharmacy Program

The University of North Carolina at Chapel Hill School of Pharmacy is accepting applications for the fifth entering class of the External Doctor of Pharmacy Program from Feb. 1 through May 1 for the Fall 1999 semester. Applications will be available on Jan. 1. If you would like an application or additional information about the Program, contact:

Pamela Joyner, EdD, MS.,
Associate Dean for Professional Education,
UNC-CH School of Pharmacy
Beard Hall - CB #7360
Chapel Hill, NC 27599-7369

Phone: (800)257-3561or (919) 962-5000
fax: 919-966-8374
e-mail: cathy_hardee@unc.edu

Nominations for New NCSHP Officers

The following slate of candidates was presented by the nominations committee at the NCSHP Business Meeting on Oct. 6. The committee consists of chairman Tim Giddens, Judy Crouch, Tom Hughes, John Pieper, Lori Poole and Jackie Roh.

Nominations for President-Elect

- Vance Collins, Halifax Regional Medical Center
- Wallace Nelson, Chowan Hospital

Nominations for Executive Secretary

- Fred Eckel, UNC School of Pharmacy

Nominations for Board of Directors (2 positions)

- Lynne Alexander, Duke University Medical Center
- Craig Coumbe, Cape Fear Valley Medical Center
- Joe Johnson, Moses Cone Memorial Hospital
- Billy Smith, Carteret General Hospital

Nominations for Delegate to the ASHP House of Delegates (1 position)

- Vance Collins, Halifax Regional Medical Center
- Wallace Nelson, Chowan Hospital
- Bill Harris, Duke University Medical Center

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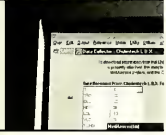

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Patient Counseling: Chronic Cancer Pain; Part 1

Thomas A. Gossel, R.Ph., Ph.D.,
Dean, and Professor of
Pharmacology and Toxicology
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph.,
PharmD.
Professor of Pharmacy Practice
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Cincinnati, Ohio

Goals. The goals of this lesson are to discuss chronic cancer pain, and present information useful in counseling patients and their caregivers about how to manage this condition.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. differentiate between characteristics of various types of pain;
2. choose from a list those components that distinguish the chronic pain syndrome from other types of pain;
3. exhibit knowledge of the drug treatment options for chronic cancer pain;
4. show an understanding of the pharmacologic actions and adverse effects associated with drugs used to treat chronic cancer pain; and,
5. demonstrate knowledge on how to counsel patients and their caregivers on controlling chronic cancer pain.

A professional development program made possible by an educational grant from

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Each year more than one million Americans are diagnosed with cancer. Cancer pain is chronic and a major cause of anxiety, anger, depression, and loss of self-esteem. Up to 45 percent of all cancer patients experience moderate to severe pain. Thus, pain in cancer patients is a problem of intensive proportion.

Chronic cancer pain can be controlled in 85 to 95 percent of patients when the basic guidelines of therapy are followed closely. Unfortunately, too many cancer patients suffer needlessly because their pain is frequently undertreated due to misunderstanding of basic principles of pharmacotherapy, or to social stigma to opioid analgesics harbored by the patients themselves and their healthcare provider.

Chronic Cancer Pain

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or is described in terms of such damage. It is more than simple, uncomplicated nociception (i.e., stimulation of a neuron).

Pain is a subjective experience that also includes the manner in which the stimulus is perceived and expressed. There are no reliable pharmacologic, neurologic or behavioral tests to measure or describe its intensity. Therefore, it is impossible for a healthy person who has not experienced it to ever know how a cancer patient who suffers from chronic pain feels.

The most common type of chronic cancer pain is somatic pain (Table 1). This is usually described as aching or gnawing, and it is constant. Pain from bone metastases is an example. Somatic pain results from stimulation of nociceptors or sensory receptors. Visceral pain is usually described the same way. It is caused by stretching or distention of abdominal and thoracic viscera. Neuropathic pain is perceived as burning, tingling, sharp and/or shooting. Both somatic and visceral pain respond to non-opioid, opioid or adjuvant analgesics. Neuropathic pain can be managed with tricyclic antidepressants or anticonvulsants in many patients.

Unrelieved pain reduces appetite and physical activity. It interferes with sleep which intensifies the patient's weakness. When patients suffer severe pain, they frequently are depressed, cannot work, and suffer low self-esteem.

Pain control in cancer patients is best achieved when healthcare providers can interpret the patient's pain correctly. With appropriate use of available medications, the majority of patients can experience significant relief and enhanced comfort.

Pain management improves the patient's quality of life. It involves addressing the patient's emotional, spiritual, and physical needs, and those of the family.

Reimbursement issues must also be addressed. The most appropriate therapy may not qualify for reimbursement, may be too costly, or simply may not be available.

Analgesic Use

Pharmacologic management is the cornerstone of therapy for chronic cancer pain. It is effective, safe, and reasonable in cost. Even within the same family of drugs, individual variability to each drug in effectiveness and adverse reactions can be significant.

Flexibility is the key to management of chronic pain. When the patient's needs change, medication dosage should be adjusted upward or downward, or the drug added to or changed completely without delay. The patient's description of outcome of therapy should always be accepted as the most reliable assessment of suitability of therapy.

Table 1
Types of Pain

Type	Characteristics	Treatment
Somatic	constant, well-localized, aching, gnawing, throbbing	analgesics, nerve blocks (opioid-sensitive)
Visceral	diffuse, deep, dull, cramping, squeezing	analgesics, more complex neurosurgical procedures
Neuropathic	altered sensations, stabbing, burning, tingling, constant or intermittent	tricyclic antidepressants, anticonvulsants, neurological procedures (opioid insensitive)

Opioid analgesics range from mild drugs such as codeine and propoxyphene, to stronger drugs such as morphine, fentanyl, and related compounds. Non-analgesic adjuvant drugs may be added to a therapy protocol to augment pain relieving activity. Unlike nonsteroidal anti-inflammatory drugs (NSAIDs) which have a ceiling effect for analgesia, opioid action, except for codeine, propoxyphene, and buprenorphine, are dose-dependent; the greater the dose, the more intense the analgesia. Because of their ceiling doses, codeine and propoxyphene are commonly used in combination products to treat mild to moderate pain, and buprenorphine's use is limited.

Opioids

Opioids are the major class of analgesics used in management of moderate to severe pain. They are effective, easily titrated, and have a favorable benefit-to-risk ratio. They are classified into three categories: full agonists (i.e., morphine-like), partial agonists, or mixed agonist-antagonists, depending on the specific receptors to which they bind and their activity at these receptors.

There are a number of morphine-sensitive receptors involved in perception and reaction to pain. Referred to as *opioid receptors,* they are further subclassed as delta, kappa, mu and sigma. Mu receptors are considered to be the ones most involved with pain and euphoria. As will be seen, different centrally-active analgesics react with these four receptors in different ways.

Morphine. The prototypical drug to treat severe cancer pain, morphine sets the standard to which all other analgesics are compared. Derivatives of morphine differ quantitatively, but possess similar qualitative pharmacologic actions including beneficial and adverse effects.

Morphine has the greatest acceptance rate, partly because of drug-induced euphoria which helps in pain control. Its low cost is also an important consideration for long-term therapy.

The World Health Organization (WHO) recognizes that cancer pain is an international problem. It has, therefore, stated that every nation should make treatment of chronic cancer pain a high priority. It has suggested that oral morphine is the drug of choice for management of chronic pain. Parameters that contribute to its safe use in cancer patients include its plasma half-life of two to three hours which is shorter than its duration of analgesia. This limits its accumulation.

Morphine products are available in both short-acting and long-acting formulations. The long-acting forms may be dosed every eight to 12 hours, or with some, every 12 to 24 hours. Moreover, morphine does not induce its own metabolism with continued dosing.

Hydromorphone. Because of its short half-life of two to three hours, hydromorphone (Dilaudid) is a logical alternative to morphine in elderly cancer patients who cannot tolerate it. Hydromorphone is as effective as morphine in analgesia, but causes greater CNS sedation.

Fentanyl. This (and other drugs in its class, i.e., alfentanil, remifentanil, sufentanil) is an extremely potent opioid with a short half-life of three to four hours. Its major use is to control pain in minor surgical procedures for which it provides sufficient analgesia to eliminate the need for a general anesthetic. Fentanyl required parenteral administration until recently. The others still do.

With marketing of a trans-dermal patch system (Duragesic), fentanyl's usefulness improved. The transdermal patches release the drug at a steady rate over 72 hours. Onset of analgesia after initial application may require 12 to 24 hours. Breakthrough medication, usually morphine, should be provided. A suggested dose is 15 percent of the 24-hour fentanyl dose. Because of the long duration of action, dose titration is difficult, especially in elderly patients.

Meperidine. Meperidine (Demerol) is useful in controlling acute pain over a few days. It is not an acceptable choice for management of chronic cancer pain and should be excluded from this use. A toxic metabolite, normeperidine, can accumulate with chronic dosing resulting in CNS hyperexcitability, described later. Conditions which favor accumulation of this metabolite include high doses, repetitive dosing, or impaired renal or hepatic function.

Oxycodone. Available alone or in combination with acetaminophen or aspirin, oxycodone (in Percocet, Percodan, etc.) and **hydrocodone** (in Lortab, Vicodin, etc.) are useful in patients who do not respond to less potent narcotics.

Codeine with Aspirin/Acetaminophen. Codeine is usually combined with aspirin or acetaminophen for its additive action. Thirty milligrams of codeine are approximately equal in analgesic potency to 325 to 600 mg aspirin. Unlike morphine, codeine is approximately 60 percent as effective orally as parenterally. Codeine has a low affinity for opioid receptors. Its analgesic effect is due to conversion to morphine.

Mixed Agonist-Antagonist Analgesics. Butorphanol (Stadol), nalbuphine (Nubain), denocine (Dalgan), and pentazocine (Talwin) block or are neutral at one type of opioid receptor while activating a different opioid receptor. They can precipitate withdrawal in persons who have not become tolerant to opioids.

If they are going to be tried, it should be before, not after, chronic administration of morphine-like drugs. In therapeutic doses, these drugs can cause self-limiting psychotomimetic (i.e., produce symptoms of psychoses) actions. They have a limited role in treating chronic cancer pain.

Opioid Dosing

There is significant variation among patients in how they respond to opioid-induced analgesia, shown by the minimal effective analgesic concentration (MEAC) required to manage severe pain. While consistent for some persons, the MEAC may represent a many-fold difference in dosage for others. For example, the intersubject MEAC for meperidine varied from 94 to 754ng/mL in one study of six persons. This represented an eight-fold difference in drug requirement between patients at the ends of the spectrum. Morphine's MEAC is reported to be 16ng/mL with a range of six to 33ng/mL.

The fundamental principle in controlling chronic cancer pain is to individualize therapy. This involves selecting the proper analgesic and tailoring its dose to each person's needs. The WHO developed a three-step hierarchy process for analgesic pain management. Alternate drugs should be substituted within a category before switching therapy.

The initial step in this three-step analgesic ladder uses the simplest dosage schedules with the least invasive pain management modalities. For mild to moderate pain, aspirin, acetaminophen or NSAIDs should be used unless specifically contraindicated (Step 1). When pain persists or increases, an opioid should be added (Step 2). If pain continues or becomes moderate to severe, the opioid potency or dose should be increased (Step 3). It should be realized that not all patients will begin therapy at Step 1 of the analgesic ladder because of the severity and type of pain.

Once their requirements have been determined for a 24-hour period by titration using an *as needed* dosing schedule, patients with persistent pain should receive regularly spaced doses. This is particularly important for drugs with a long half-life.

After the patient's needs are established, an around-the-clock dosing schedule can reduce the total amount of drug needed per day. It normally requires less total drug to prevent pain recurrence than to ameliorate it once it reappears. This also reduces intense variations in peak and trough concentrations which minimize some adverse effects such as sedation.

Some patients may require an occasional supplemental (i.e., rescue) dose of a short-acting formulation product to provide uninterrupted analgesia. Of greater importance is the comfort this schedule can provide the patient. It can essentially maintain the patient pain-free. When breakthrough pain occurs, rescue doses can be calculated for most patients by using five to 15 percent of the total daily dose, and administering the dose every two to three hours in addition to the scheduled drug, depending on the drug's pharmacokinetic profile. The drug used for rescue should be an immediate-release dosage form, ideally the same drug as the scheduled one.

If it becomes necessary to switch from one opioid to another, change should proceed from an opioid of lower effectiveness to one of greater analgesic effect. It must be remembered that conversion tables for equianalgesic doses (Table 2) apply to non-tolerant patients.

Routes of Administration

Oral. Many patients with chronic cancer pain can swallow medication satisfactorily. For them, oral dosing is the most convenient, and usually least expensive route of drug administration. It should be considered first. In general, orally-administered drugs have a slower onset of action, delayed peak time, and a longer duration of action compared to parenterally-administered agents. For patients who are unable to swallow solid dosage forms, or when high doses of opioids are needed, oral solution products are available.

When patients cannot take oral medications, other less invasive (e.g., rectal or transdermal) routes should be offered. Parenteral routes should be used only when simpler, less demanding and less costly methods are inappropriate or ineffective.

Rectal. Rectal administration offers an alternate choice to the parenteral route for patients who cannot take opioids orally. Suppositories are suitable for patients who have nausea or are vomiting. Rectal administration is inappropriate when the patient has diarrhea, anal/rectal lesions, or mucositis. It is also inappropriate

Table 2
Dose Equivalents for Opioid Analgesics*

Drug	Approx. Equianalgesic Dose		Usual Starting Dose (mod. to severe pain)	
	Oral	Parenteral	Oral	Parenteral
Morphine	30mg q 3-4 hr around clock or 60 mg q 3-4 hr (single or intermittent dosing)	10mg q 3-4 hr	30mg q 3-4 hr	10mg q 3-4 hr
Morphine (controlled release)	90-120mg q 12 hr	——	90-120mg q 12 hr	——
Hydromorphone	7.5mg q 3-4 hr	1.5mg q 3-4 hr	6mg q 3-4 hr	1.5 mg q 3-4 hr
Meperidine	300mg q 2-3 hr	100mg q 3 hr	——	100mg q 3 hr
Methadone	20mg q 6-8 hr	10mg q 6-8 hr	20mg q 6-8 hr	10mg q 6-8 hr
Oxymorphone	——	1mg q 3-4 hr	——	1mg q 3-4 hr

*For patients weighing 50kg or more. Table adapted from Table 4, AHCPR Publication No. 94-0593. U.S. Department of Health and Human Services, p. 10.

for patients who have thrombocytopenia (decreased platelets) or neutropenia (decreased neutrophils — one of the white blood cells), or those unable to place the suppository into the rectum.

Intravenous. Drugs given as a bolus intravenously provide the most rapid onset and shortest duration of action. Continuous intravenous infusion is useful for individuals who cannot take oral opioids, and those requiring continuous intravenous access for other purposes. It provides complete absorption, and intermittent bolus doses can be given to supplement infusion when needed. When intravenous access is not feasible, subcutaneous opioid infusion is practical in the hospital or home.

Patient Controlled Analgesia (PCA). When orally or intramuscularly-administered opioids are no longer effective for maintaining patient comfort, she or he can be supplied with a PCA set-up. This consists of the drug in a metered pump to be delivered intravenously, subcutaneously, or epidurally (intraspinally). The patient can control the drug administration and, thus, pain control. The patient, within limits, titrates the dose to personal requirements. PCA is safe and effective for ambulatory patients. Limitations to PCA include the need for intravenous access and an infusion pump. Today, these units are readily available from Home Health Care providers and covered by most insurance programs.

Intraspinal Injection. Placing the drug directly into the cerebrospinal fluid blocks nociceptive impulses from the periphery to the brain. This induces analgesia without diminution of motor or sensory receptors. It also minimizes the chance of adverse effects since the drug is not given systemically.

This invasive route can be considered for patients who develop intractable pain or intolerable adverse effects with other routes. The main indication for long-term administration of intraspinal opioids is for treatment of intractable pain in the lower part of the body, particularly bilateral or midline pain.

Placement of an intraspinal catheter is an invasive technique that involves its own risks. Intraspinal injection is usually reserved for persons who fail to respond to other methods of administration of systemic drugs.

Transdermal Patches. Transdermal patches are not suitable for relief of acute pain or rapid dose titration. Hence, this route is used for chronic, relatively stable pain when rapid increases or decreases in intensity are not likely to occur.

Summary

Part II of this two-part lesson series describes adverse effects to opioids, the use of adjuvant drugs and non-drug treatments of chronic cancer pain, and information to use when counseling patients and/or their caregivers.

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Continuing Education Quiz

Patient Counseling: Chronic Cancer Pain; Part 1

1. The term "simple" uncomplicated nociception, when relating to chronic pain, refers to pain:
   a. that is psychosomatic and nonexistent.
   b. of unknown cause.
   c. that occurs in a hospital after the patient has been admitted.
   d. caused by stimulation of a neuron.

2. Morphine has the greatest acceptance rate among opioids in treating cancer pain because:
   a. it induces its own metabolism with continuous therapy.
   b. its drug-induced euphoria helps in pain control.
   c. it is less addicting than the other opioids.
   d. it is available in an injectable dosage form.

3. The fundamental principle in controlling chronic cancer pain is to:
   a. avoid addicting drugs.
   b. individualize therapy.
   c. give the drug with the longest duration of action.
   d. use the strongest analgesic.

4. The type of pain that is perceived as a constant, well-localized, aching, gnawing or throbbing sensation is referred to as:
   a. neuropathic pain.
   b. visceral pain.
   c. somatic pain.
   d. nosocomial pain.

5. The opioid that is most likely to be effective in managing chronic cancer pain would have high activity at which of the following subclasses of opioid receptors?
   a. Delta
   b. Kappa
   c. Mu
   d. Sigma

6. Pain that is perceived as a diffuse, deep, dull, cramping or squeezing sensation is:
   a. neuropathic pain.
   b. visceral pain.
   c. somatic pain.
   d. nosocomial pain.

7. Which of the following types of opioid drugs would be LEAST likely to be an effective analgesic?
   a. A full opioid agonist
   b. A partial opioid agonist
   c. A mixed opioid agonist-antagonist
   d. A full opioid antagonist

8. The type of pain that is most likely to be managed by therapy with a tricyclic antidepressant is:
   a. neuropathic pain.
   b. visceral pain.
   c. somatic pain.
   d. nosocomial pain.

9. The opioid that is commercially available in a transdermal patch is:
   a. fentanyl.
   b. hydromorphone.
   c. meperidine.
   d. morphine.

10. All of the following are mixed agonist-antagonist analgesics EXCEPT:
   a. nalbuphine.
   b. butorphanol.
   c. pentazocine.
   d. meperidine.

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Small Doses

• **Maureen McMormick**, CPhT, Head Technician of Ward Drug Co. in Nashville, NC, was named to the 7-member APhA Pharmacy Technician Advisory Committee to help advise the Association on matters related to the new pharmacy technician category of membership. ... • **Judith Schnetzka Groves** of Reidsville was selected to participate in the ASCP Research and Education Foundation's Wound Care Traineeship for Consultant Pharmacists. ... • **Charlotte Matheny Mize** of Greensboro was selected by ASCP Research and Education Foundation's Disease Pharmacotherapy Traineeship for Consultant Pharmacists. ... • **Dennis M. Williams**, assistant professor at UNC-CH School of Pharmacy and a clinical specialist in pulmonary medicine for UNC Hospitals, has been voted Chair-elect of the American Society of Health-System Pharmacist Section of Clinical Specialists. ... • The Board of Pharmaceutical Specialities announced the members of five pharmacotherapy item writing panels. The following were named from North Carolina: Cardiology - **J. Herbert Patterson**, Chapel Hill; Infectious Diseases - **Roy A. Pleasants**, Chapel Hill; **Ralph H. Raasch** (Chair), Chapel Hill; Primary Care - **Timothy J. Ives**, Efland; **Julienne K. Kirk**, Winston-Salem; **J. Michael Spivey**, Apex; Domain Three - **John Michael Kessler**, Carrboro. ... • **Gianna N. Bryan** of Winterville, **Terri B. Cardwell** of Clemmons, **Patricia A. Cash** of Stanley, **Annette A. Collette** of Hickory, **Rebekah M. Collins Satko** of Clemmons, **Melaine L. Evans** of Raleigh, **Wendy R. Holmes** of Wendell, **Margaret A. Sgritta** of Moorseville, **James H. Strickland Jr.** of Wilmington and **Marla L. Styons** of Wilmington have been accredited as Certified Geriatric Pharmacists by the Commission for Certification in Geriatric Pharmacy. ... • **CVS/Pharmacy** officially changed the names of their stores previously named Revco on Oct. 9. A Grand-opening celebration was held in Raleigh. ... •**Charles H. Gaddy** of Clinton died on Aug. 9, 1998, at Sampson Regional Medical Center. He worked as a pharmacist at McLean Drug before opening Gaddy Pharmacy. He graduated from UNC School of Pharmacy in 1950. ... • **Barry Vernon Gates** of Mount Airy died Sept. 9, 1998, at Northern Hospital of Surry County after sustaining a heart attack. He was the owner and pharmacist of The Medicine Shoppe. He graduated from UNC School of Pharmacy in 1977.

Letters to the Editor

Dear CJP,

The heart and soul of the Pharmacy Practice Act has undergone major bypass surgery as well as resurrections on several occasions during the 1998 Short Session of the Legislature. We must all give credit to Rep. Edd Nye for his diligent work in attempting to keep the bill alive and moving forward. This bill was only the beginning of the process by which we must convince the public and our healthcare colleagues that pharmaceutical care from a pharmacist is the way we should be practicing.

One major issue that kept the bill in tact for a while was the Board of Pharmacy composition. I really do not believe anyone would argue that one member representative from a health care facility on our board would be anything but in the best interest of the public we serve. While there were many people who worked tirelessly to try to get this section of the bill passed, Billy Smith from Carteret General in Morehead City led the efforts for Pharmacy Practice to move forward and practice site composition to be the reflective face of our Board.

We were all very hopeful about getting the Pharmacy Practice Act through legislation. But we have learned the hard way what you must do in order for a major bill to proceed through this process so it looks anything like coming out as it did going in. Let's just hope next year we can count on the Edd Nyes and Billy Smiths to be there to work diligently for us again.

Hunt Taylor, Duplin General Hospital
hunt@interstar.net

Dear CJP,

Why do we have laws passed for the protection and safety of the general public forcing us to take the time to talk to each customer explaining to them everything they should know about their medicines and the do's & don't's about it? Then in the next breath these same people pass laws which let insurance companies and mail order companies bypass these same laws. Why is it they say we must be in the building when the medicines are handed out, and that a piece of paper will not be an alternative for this? How do mail order companies talk personally to the patient? Is their pharmacist in the house when meds are delivered? I have many more questions about the two tiers of laws that exist. One set is for the protection and safety of the general public (the set I have to and do go by) and the other set is for the protection and safety of the mail order companies. ...

Steven C. Harris, Beach Pharmacy of Hatteras
beachrx@interpath.com

(Mr. Harris has written to his state rep. and has much more information if you are interested in reading more.)

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SYNTHROID Injection – for parenteral administration

CONTRAINDICATIONS SYNTHROID is contraindicated in patients with untreated thyrotoxicosis of any etiology or an apparent hypersensitivity to thyroid hormones or any of the inactive product constituents (The 50 mcg tablet is formulated without color additives for patients who are sensitive to dyes.) There is no well-documented evidence of true allergic or idiosyncratic reactions to thyroid hormone. SYNTHROID is also contraindicated in the patients with uncorrected adrenal insufficiency as thyroid hormones increase tissue demands for adrenocortical hormones and may thereby precipitate acute adrenal crisis (see **PRECAUTIONS**).

WARNINGS Thyroid hormones, either alone or together with other therapeutic agents, should not be used for the treatment of obesity. In euthyroid patients, doses within the range of daily hormonal requirements are ineffective for weight reduction. Larger doses may produce serious or even life threatening manifestations of toxicity, particularly when given in association with sympathomimetic amines such as those used for their anorectic effects.

The use of SYNTHROID in the treatment of obesity, either alone or in combination with other drugs, is unjustified. The use of SYNTHROID is also unjustified in the treatment of male or female infertility unless this condition is associated with hypothyroidism.

PRECAUTIONS General SYNTHROID should be used with caution in patients with cardiovascular disorders, including angina, coronary artery disease, and hypertension, and in the elderly who have a greater likelihood of occult cardiac disease. Concomitant administration of thyroid hormone and sympathomimetic agents to patients with coronary artery disease may increase the risk of coronary insufficiency.

Use of SYNTHROID in patients with concomitant diabetes mellitus, diabetes insipidus or adrenal cortical insufficiency may aggravate the intensity of their symptoms. Appropriate adjustments of the various therapeutic measures directed at these concomitant endocrine diseases may therefore be required. Treatment of myxedema coma may require simultaneous administration of glucocorticoids (see **DOSAGE AND ADMINISTRATION**).

T_4 enhances the response to anticoagulant therapy. Prothrombin time should be closely monitored in patients taking both SYNTHROID and oral anticoagulants, and the dosage of anticoagulant adjusted accordingly.

Seizures have been reported rarely in association with the initiation of levothyroxine sodium therapy, and may be related to the effect of thyroid hormone on seizure threshold.

Lithium blocks the TSH-mediated release of T_4 and T_3. Thyroid function should therefore be carefully monitored during lithium initiation, stabilization, and maintenance. If hypothyroidism occurs during lithium treatment, a higher than usual SYNTHROID dose may be required.

Laboratory Tests Treatment of patients with SYNTHROID requires periodic assessment of adequacy of titration by appropriate laboratory tests and clinical evaluation. Selection of appropriate tests for the diagnosis and management of thyroid disorders depends on patient variables such as presenting signs and symptoms, pregnancy, and concomitant medications. A combination of sensitive TSH assay and free T_4 estimate (free T_4, free T_4 index) are recommended to confirm a diagnosis of thyroid disease. Normal ranges for these parameters are age-specific in newborns and younger children.

TSH alone or initially may be useful for thyroid disease screening and for monitoring therapy for primary hypothyroidism as a linear inverse correlation exists between serum TSH and free T_4. Measurement of total serum T_4 and T_3 resin T_3 uptake, and free T_3 concentrations may also be useful. Antithyroid microsomal antibodies are an indicator of autoimmune thyroid disease. The presence of positive microsomal antibodies in an euthyroid patient is a major risk factor for the future development of hypothyroidism. An elevated serum TSH in the presence of a normal T_4 may indicate subclinical hypothyroidism. Intracellular resistance to thyroid hormone is quite rare, and is suggested by clinical signs and symptoms of hypothyroidism in the presence of high serum T_4 levels. Adequacy of SYNTHROID therapy for hypothyroidism of pituitary or hypothalamic origin should be assessed by measuring free T_4, which should be maintained in the upper half of the normal range. Measurement of TSH is not a reliable indicator of response to therapy for this condition. Adequacy of SYNTHROID therapy for congenital and acquired pediatric hypothyroidism should be assessed by measuring serum total T_4 or free T_4, which should be maintained in the upper half of the normal range. In congenital hypothyroidism, normalization of serum TSH levels may lag behind normalization of serum T_4 levels by 2 to 3 months or longer. In rare patients serum TSH remains relatively elevated despite clinical euthyroidism and age-specific normal levels of T_4 or free T_4.

Drug Interactions The magnitude and relative clinical importance of the effects noted below are likely to be patient-specific and may vary by such factors as age, gender, race, intercurrent illnesses, dose of either agent, additional concomitant medications, and timing of drug administration. Any agent that alters thyroid hormone synthesis, secretion, distribution, effect on target tissues, metabolism, or elimination may alter the optimal therapeutic dose of SYNTHROID.

Adrenocorticoids–Metabolic clearance of adrenocorticoids is decreased in hypothyroid patients and increased in hyperthyroid patients, and may therefore change with changing thyroid status.

Amiodarone–Amiodarone therapy alone can cause hypothyroidism or hyperthyroidism.

Anticoagulants (oral)–The hypoprothrombinemic effect of anticoagulants may be potentiated, apparently by increased catabolism of vitamin K-dependent clotting factors.

Antidiabetic agents (insulin, sulfonylureas)–Requirements for insulin or oral antidiabetic agents may be reduced in hypothyroid patients with diabetes mellitus, and may subsequently increase with the initiation of thyroid hormone replacement therapy.

β-adrenergic blocking agents–Actions of some beta-blocking agents may be impaired when hypothyroid patients become euthyroid.

Cytokines (interferon, interleukin)–Cytokines have been reported to induce both hyperthyroidism and hypothyroidism.

Digitalis glycosides–Therapeutic effects of digitalis glycosides may be reduced. Serum digitalis levels may be decreased in hyperthyroidism or when a hypothyroid patient becomes euthyroid.

Ketamine–Marked hypertension and tachycardia have been reported in association with concomitant administration of levothyroxine sodium and ketamine.

Maprotiline–Risk of cardiac arrhythmias may increase.

Sodium iodide (^{123}I and ^{131}I), sodium pertechnetate Tc99m–Uptake of radiolabeled ions may be decreased.

Somatrem somatropin—Excessive concurrent use of thyroid hormone may accelerate epiphyseal closure. Untreated hypothyroidism may interfere with the growth response to somatrem or somatropin.

Theophylline—Theophylline clearance may decrease in hypothyroid patients and return toward normal when a euthyroid state is achieved.

Tricyclic antidepressants—Concurrent use may increase the therapeutic and toxic effects of both drugs, possibly due to increased catecholamine sensitivity. Onset of action of tricyclics may be accelerated.

Sympathomimetic agents—Possible increased risk of coronary insufficiency in patients with coronary artery disease.

Laboratory Test Interactions A number of drugs or moieties are known to alter serum levels of TSH, T_4 and T_3 and may thereby influence the interpretation of laboratory tests of thyroid function (see **Drug Interactions**):

1. Changes in TBG concentration should be taken into consideration when interpreting T_4 and T_3 values. Drugs such as estrogens and estrogen-containing oral contraceptives increase TBG concentrations. TBG concentrations may also be increased during pregnancy and in infectious hepatitis. Decreases in TBG concentrations are observed in nephrosis, acromegaly, and after androgen or corticosteroid therapy. Familial hyper- or hypo-thyroxine-binding-globulinemias have been described. The incidence of TBG deficiency is approximately 1 in 9000. Certain drugs such as salicylates inhibit the protein-binding of T_4. In such cases, the unbound (free) hormone should be measured. Alternatively, an indirect measure of free thyroxine, such as the FT_4I may be used.

2. Medicinal or dietary iodine interferes with *in vivo* tests of radioiodine uptake, producing low uptakes which may not indicate a true decrease in hormone synthesis.

3. Persistent clinical and laboratory evidence of hypothyroidism despite an adequate replacement dose suggests either poor patient compliance, impaired absorption, drug interactions, or decreased potency of the preparation due to improper storage.

Carcinogenesis, Mutagenesis, and Impairment of Fertility: Although animal studies to determine the mutagenic or carcinogenic potential of thyroid hormones have not been performed, synthetic T_4 is identical to that produced by the human thyroid gland.

A reported association between prolonged thyroid hormone therapy and breast cancer has not been confirmed and patients receiving levothyroxine sodium for established indications should not discontinue therapy.

Pregnancy: Pregnancy Category A. Studies in pregnant women have not shown that levothyroxine sodium increases the risk of fetal abnormalities if administered during pregnancy. If levothyroxine sodium is used during pregnancy, the possibility of fetal harm appears remote. Because studies cannot rule out the possibility of harm, levothyroxine sodium should be used during pregnancy only if clearly needed.

Thyroid hormones cross the placental barrier to some extent. T_4 levels in the cord blood of athyroid fetuses have been shown to be about one-third of maternal levels. Nevertheless, maternal-fetal transfer of T_4 may not prevent *in utero* hypothyroidism.

Hypothyroidism during pregnancy is associated with a higher rate of complications, including spontaneous abortion, and preeclampsia, and has been reported to have an adverse effect on fetal and childhood development. On the basis of current knowledge, SYNTHROID® (levothyroxine sodium, USP) should therefore not be discontinued during pregnancy, and hypothyroidism diagnosed during pregnancy should be treated. Studies have shown that during pregnancy T_4 concentrations may decrease and TSH concentrations may increase to values outside normal ranges. Postpartum values are similar to preconception values. Elevations in TSH may occur as early as 4 weeks gestation.

Pregnant women who are maintained on SYNTHROID should have their TSH measured periodically. An elevated TSH should be corrected by an increase in SYNTHROID dose. After pregnancy the dose can be decreased to the optimal preconception dose.

Nursing Mothers Minimal amounts of thyroid hormones are excreted in human milk. Thyroid hormones are not associated with serious adverse reactions and do not have known tumorigenic potential. While caution should be exercised when SYNTHROID is administered to a nursing woman, adequate replacement doses of levothyroxine sodium are generally needed to maintain normal lactation.

Pediatric Use: Congenital hypothyroidism Rapid restoration of normal serum T_4 concentrations is essential for preventing the deleterious effects of neonatal thyroid hormone deficiency on intelligence, as well as on overall growth and development. SYNTHROID should be initiated immediately upon diagnosis, and is generally continued for life. The goal of therapy is to maintain the serum total T_4 or FT_4 in the upper half of the normal range and serum TSH in the normal range.

An initial starting dose of 10 to 15 mcg/kg/day (ages 0-3 months) will generally increase serum T_4 concentrations to the upper half of the normal range in less than 3 weeks. Clinical assessment of growth and development and thyroid status should be monitored frequently. In most cases, the dose of SYNTHROID per body weight will decrease gradually as the patient grows through infancy and childhood (see Table). Prolonged use of large doses in infants may be associated with later behavior problems.

Thyroid function tests (serum total T_4 or FT_4, and TSH) should be monitored closely and used to determine the adequacy of SYNTHROID therapy. Normalization of serum T_4 levels is usually followed by a rapid decline of TSH levels. Nevertheless, normalization of TSH may lag behind normalization of T_4 levels by 2 to 3 months or longer. The relative elevation of serum TSH is more marked during the early months of therapy but can persist to some degree throughout life. In rare patients TSH remains relatively elevated despite clinical euthyroidism and age-specific normal levels of total T_4 or FT_4. Increasing the SYNTHROID dosage to suppress TSH into the normal range may result in overtreatment, with an elevated serum T_4 level and clinical features of hyperthyroidism, including irritability, increased appetite with diarrhea, and sleeplessness. Another risk of prolonged overtreatment in infants is premature cranial synostosis.

Assessment of permanence of hypothyroidism may be done when transient hypothyroidism is suspected. Levothyroxine therapy may be interrupted for 30 days after 3 years of age and serum measurement of T4 and TSH levels obtained. If T_4 is low and the TSH level is elevated, permanent hypothyroidism is confirmed and therapy should be re-instituted. If T_4 and TSH remain in the normal range, a presumptive diagnosis of transient hypothyroidism can be made. In this instance, continued clinical monitoring and periodic reevaluation of thyroid function may be warranted.

Acquired hypothyroidism. The initial dose of SYNTHROID varies with age and body weight, and should be adjusted to maintain serum total T_4 or free T_4 levels in the upper half of the normal range. In general, in the absence of overriding clinical concerns, children should be started on a full replacement dose. Children with underlying heart disease should be started at lower doses, with careful upward titration. Children with severe, long-standing hypothyroidism may also be started on a lower initial dose with upward titration in an attempt to avoid premature closure of epiphyses. The recommended dose per body weight decreases with age (see Table).

Treated children may resume growth at a rate greater than normal (period of transient catch-up growth). In some cases catch-up growth may be adequate to normalize growth; however, in children with severe and prolonged hypothyroidism, adult height may be reduced. Excessive thyroxine replacement may initiate accelerated bone maturation resulting in disproportionate advancement in skeletal age and shortened adult stature.

Assessment of permanence of hypothyroidism may be done when transient hypothyroidism is suspected. Levothyroxine therapy may be interrupted for 30 days and serum measurement of T_4 and TSH levels obtained. If T_4 is low and the TSH level is elevated, permanent hypothyroidism is confirmed and therapy should be re-instituted. If T_4 and TSH remain in the normal range, a presumptive diagnosis of transient hypothyroidism can be made. In this instance, continued clinical monitoring and periodic reevaluation of thyroid function may be warranted.

ADVERSE REACTIONS Adverse reactions other than those indicative of thyrotoxicosis as a result of therapeutic overdosage, either initially or during the maintenance periods, are rare (see **OVERDOSAGE**). Craniosynostosis has been associated with iatrogenic hyperthyroidism in infants receiving thyroid hormone replacement therapy. Inadequate doses of SYNTHROID may produce or fail to resolve symptoms of hypothyroidism. Hypersensitivity reactions to the product excipients, such as rash and urticaria, may occur. Partial hair loss may occur during the initial months of therapy but is generally transient. The incidence of continued hair loss is unknown. Pseudotumor cerebri has been reported in pediatric patients receiving thyroid hormone replacement therapy.

OVERDOSAGE: Signs and Symptoms: Excessive doses of SYNTHROID result in a hypermetabolic state indistinguishable from thyrotoxicosis of endogenous origin. Signs and symptoms of thyrotoxicosis include weight loss, increased appetite, palpitations, nervousness, diarrhea, abdominal cramps, sweating, tachycardia, increased pulse and blood pressure, cardiac arrhythmias, tremors, insomnia, heat intolerance, fever, and menstrual irregularities. Symptoms are not always evident or may not appear until several days after ingestion.

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